	Type	L #	Hits	Search Text	DBs	Time Stamp
1	IS&R	L1	1	("6623485").PN.	USPAT	2003/09/24 09:59
2	IS&R	L2	1158	(606/61).CCLS.	USPAT	2003/09/24 10:00
3	IS&R	L3	387	(606/60).CCLS.	USPAT	2003/09/24 10:00
4	IS&R	L4	408	(606/69).CCLS.	USPAT	2003/09/24 10:01
5	IS&R	L5	125	(606/70).CCLS.	USPAT	2003/09/24 10:01
6	IS&R	L6	156	(606/71).CCLS.	USPAT	2003/09/24 10:01
7	IS&R	L7	735	(606/72).CCLS.	USPAT	2003/09/24 10:02
8	IS&R	L8	813	(606/73).CCLS.	USPAT	2003/09/24 10:02
9	IS&R	L9	9	(("6309391") or ("6022350") or ("5540688") or ("5425779") or ("5176680") or ("4435101") or ("4241463") or ("4230415") or ("3568770")).PN.	USPAT	2003/09/24 10:08
10	BRS	L10	5	anchoring adj assembly & split adj retention adj ring	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/09/24 10:19

	Type	L #	Hits	Search Text	DBs	Time Stamp
11	BRS	L11	1	bone adj screw & spherical adj connector & ball adj shaped adj cavity	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/09/24 10:21

US006050997A

United States Patent [19]

Mullane

[11] Patent Number: 6,050,997

[45] Date of Patent: Apr. 18, 2000

[54] SPINAL FIXATION SYSTEM

[76] Inventor: Thomas S. Mullane, 1201 River Reach Dr., Suite 512, Ft. Lauderdale, Fla. 33315

[21] Appl. No.: 09/237,175

[22] Filed: Jan. 25, 1999

[51] Int. Cl.[7] A61B 17/56

[52] U.S. Cl. 606/61; 606/73

[58] Field of Search 606/61, 72, 73

[56] References Cited

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4,887,595	12/1989	Heinig et al. .	
4,887,596	12/1989	Sherman .	
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5,133,717	7/1992	Chopin .	
5,569,247	10/1996	Morrison .	
5,591,166	1/1997	Bernhardt et al. .	
5,716,357	2/1998	Rogozinski .	
5,725,528	3/1998	Errico et al.	606/61
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Primary Examiner—Julian W. Woo

Attorney, Agent, or Firm—McHale & Slavin PA

[57] ABSTRACT

An adjustable spinal fixation system comprises a collection of anchoring assemblies attached, via a variety of connectors, to spine-stabilizing rods. The anchoring assemblies include a linking member attached in a ball-and-socket fashion to a bone-engaging member that is adapted to engage a spinal bone of a patient. The linking member joins one of the included connectors to an associated bone-engaging member. The connectors are selectively attached to one of the stabilizing rods. The anchoring assemblies each include a support collar and a retention collet that cooperate to allow adjustment of the bone-engaging member and corresponding connector during surgery. When surgery is complete, a securing nut and locking bolt cooperate with the support collar and retention collet to maintain the relative position of the entire fixation system, preventing unwanted movement between the system components. In one embodiment, the connectors are multi-piece units that may be added or removed without disturbing adjacent connectors.

25 Claims, 9 Drawing Sheets

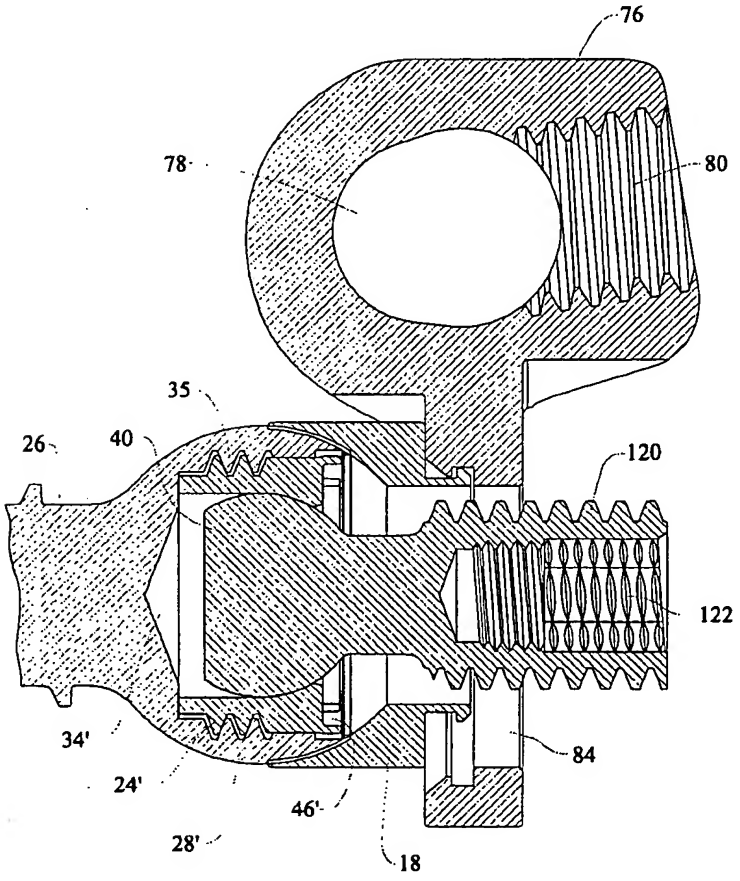


FIG. 1

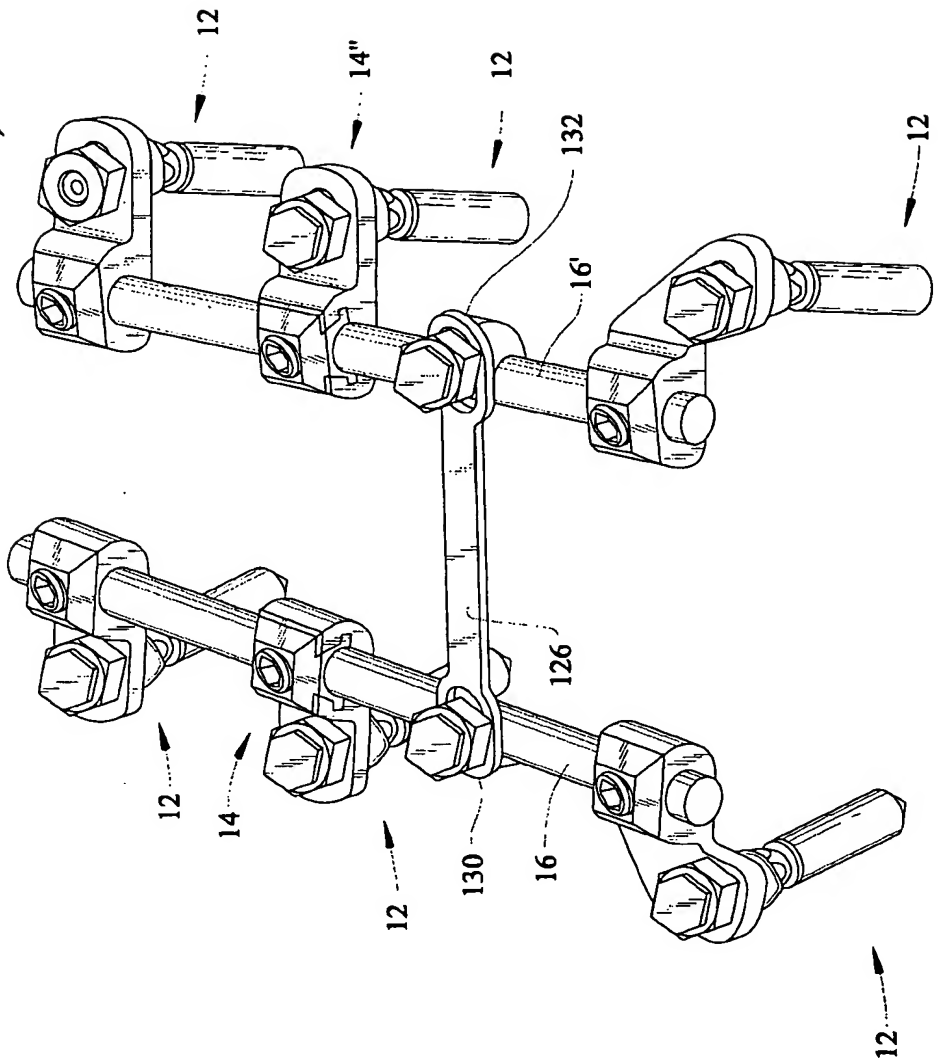


FIG. 2

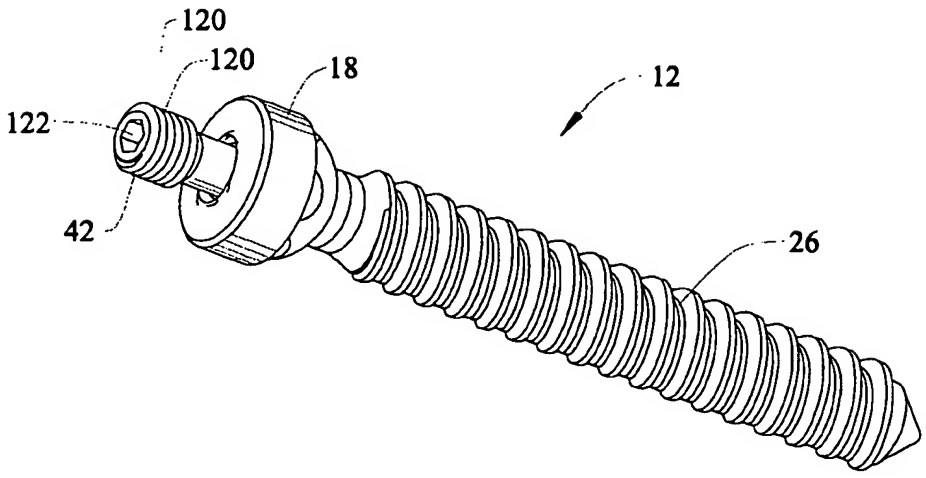


FIG. 3

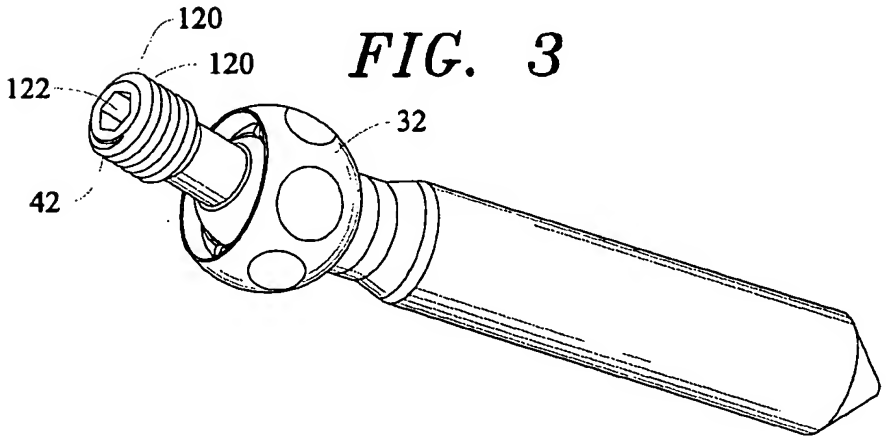


FIG. 3A

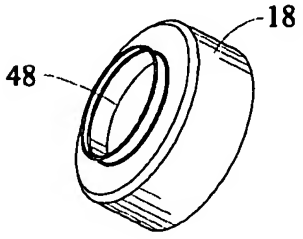


FIG. 4

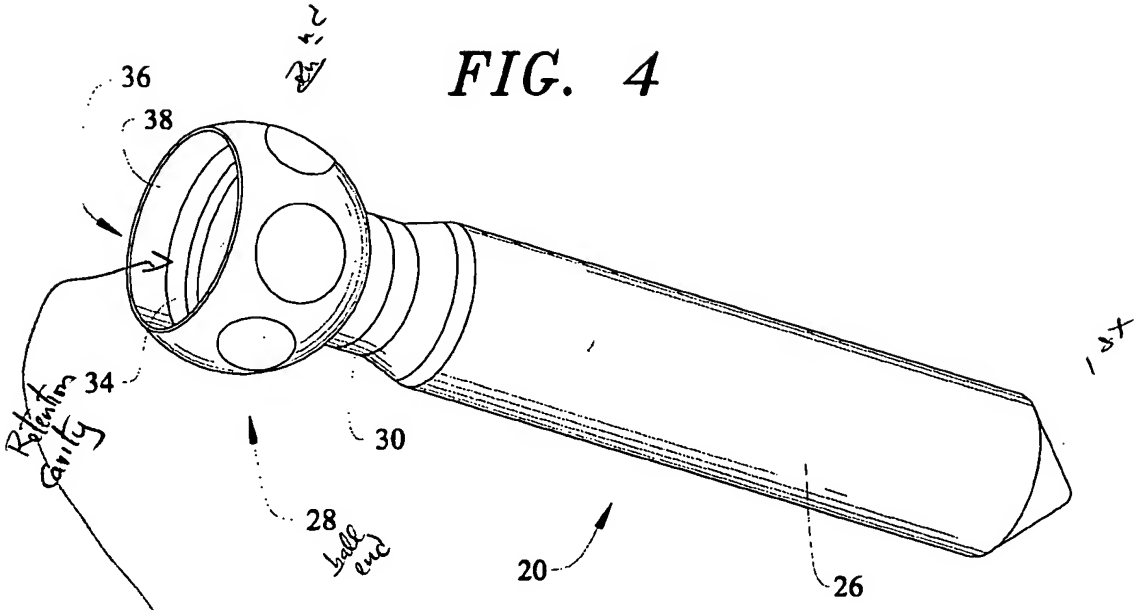


FIG. 4A

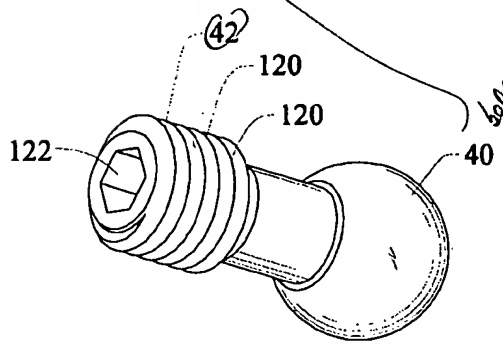


FIG. 4B

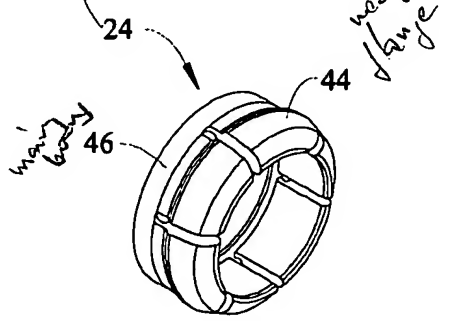


FIG. 5

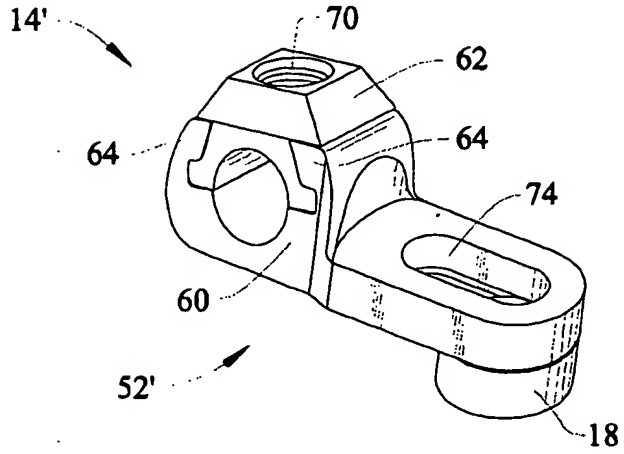


FIG. 5A

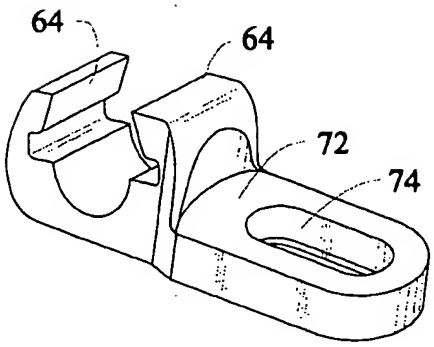


FIG. 5B

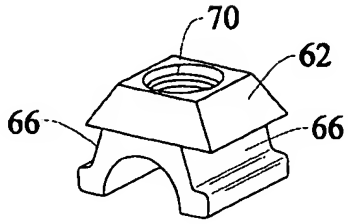


FIG. 5C

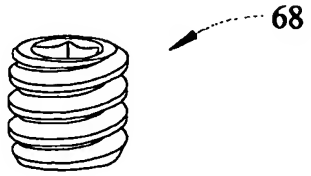


FIG. 6

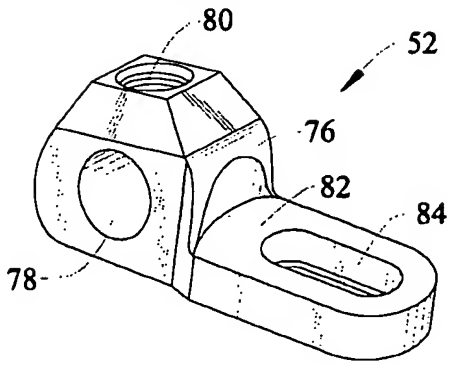


FIG. 6A

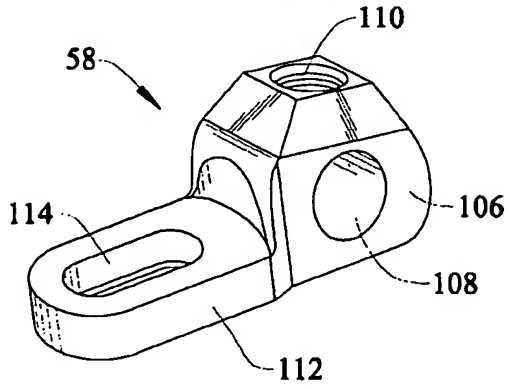


FIG. 7

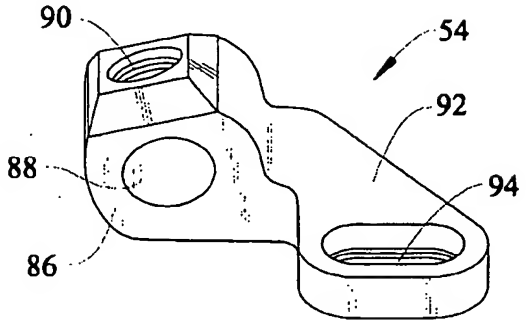


FIG. 8

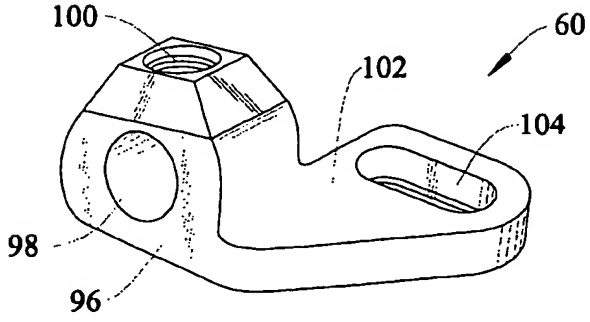


FIG. 9

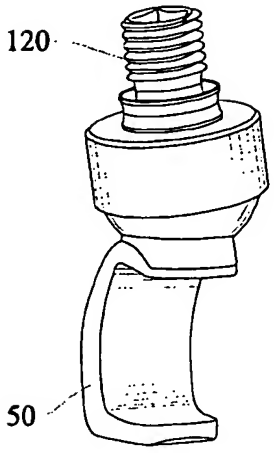


FIG. 10

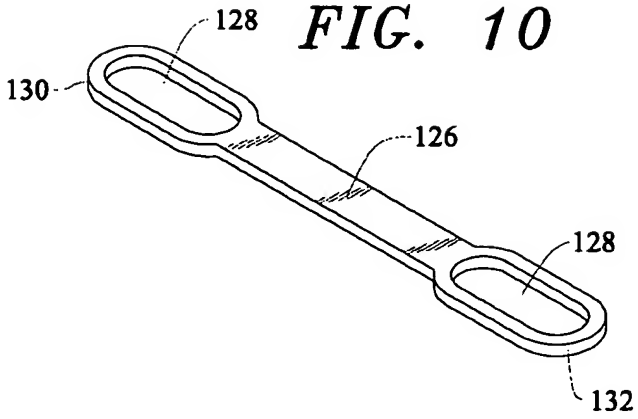


FIG. 11

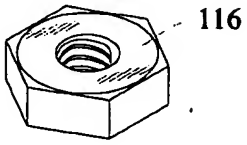


FIG. 12

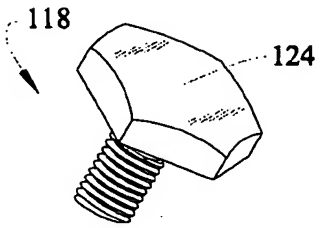


FIG. 13

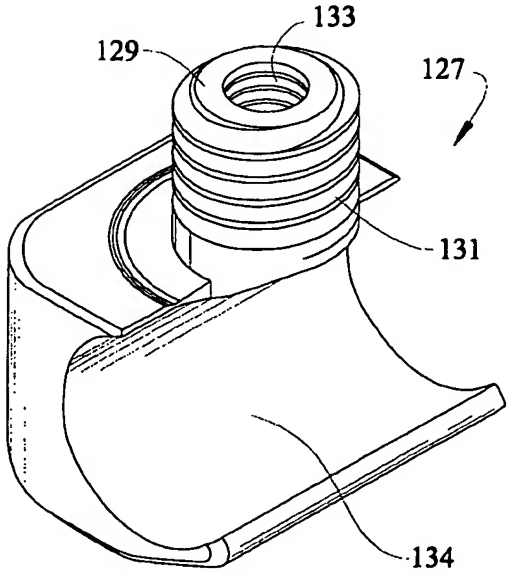


FIG. 14

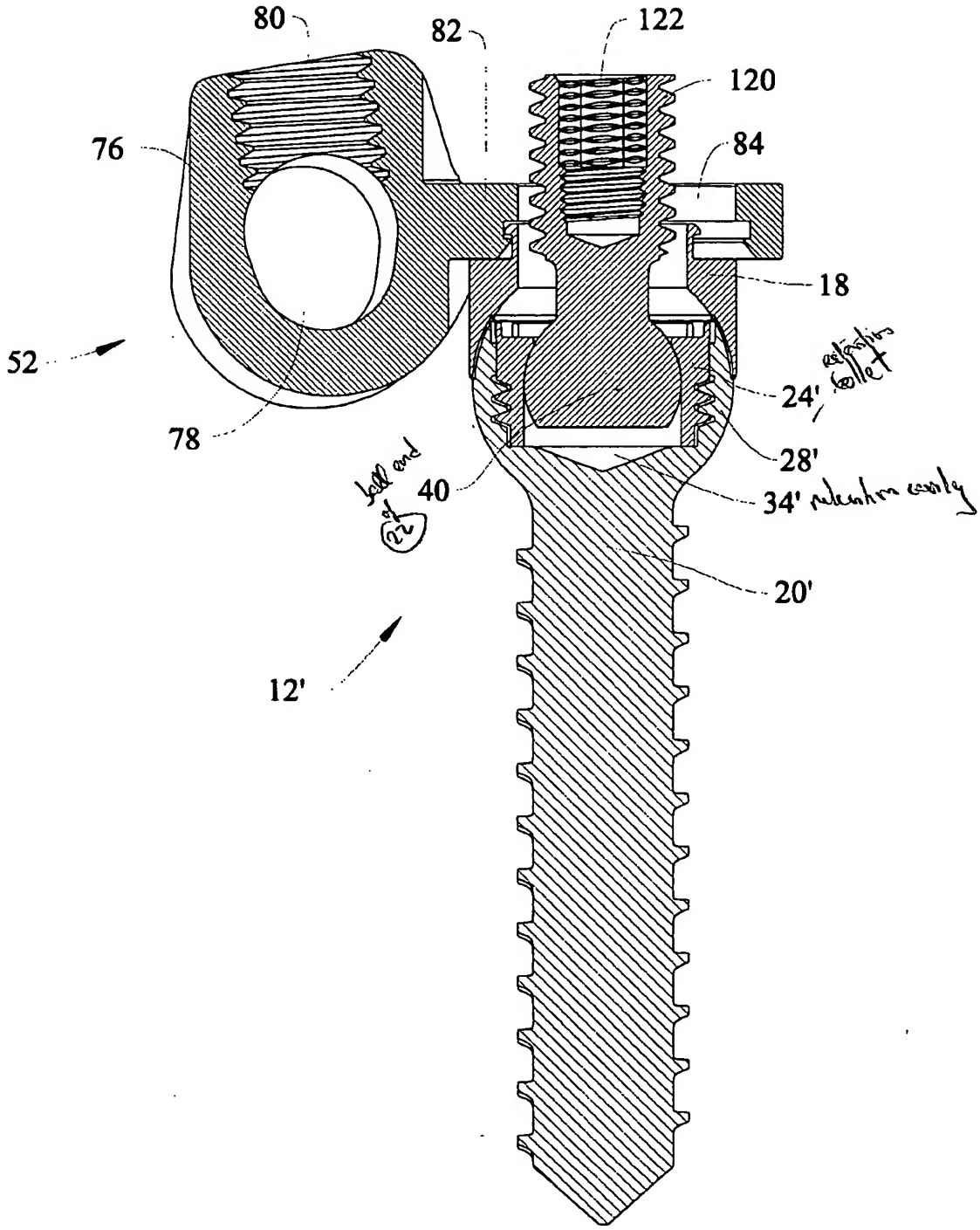


FIG. 15

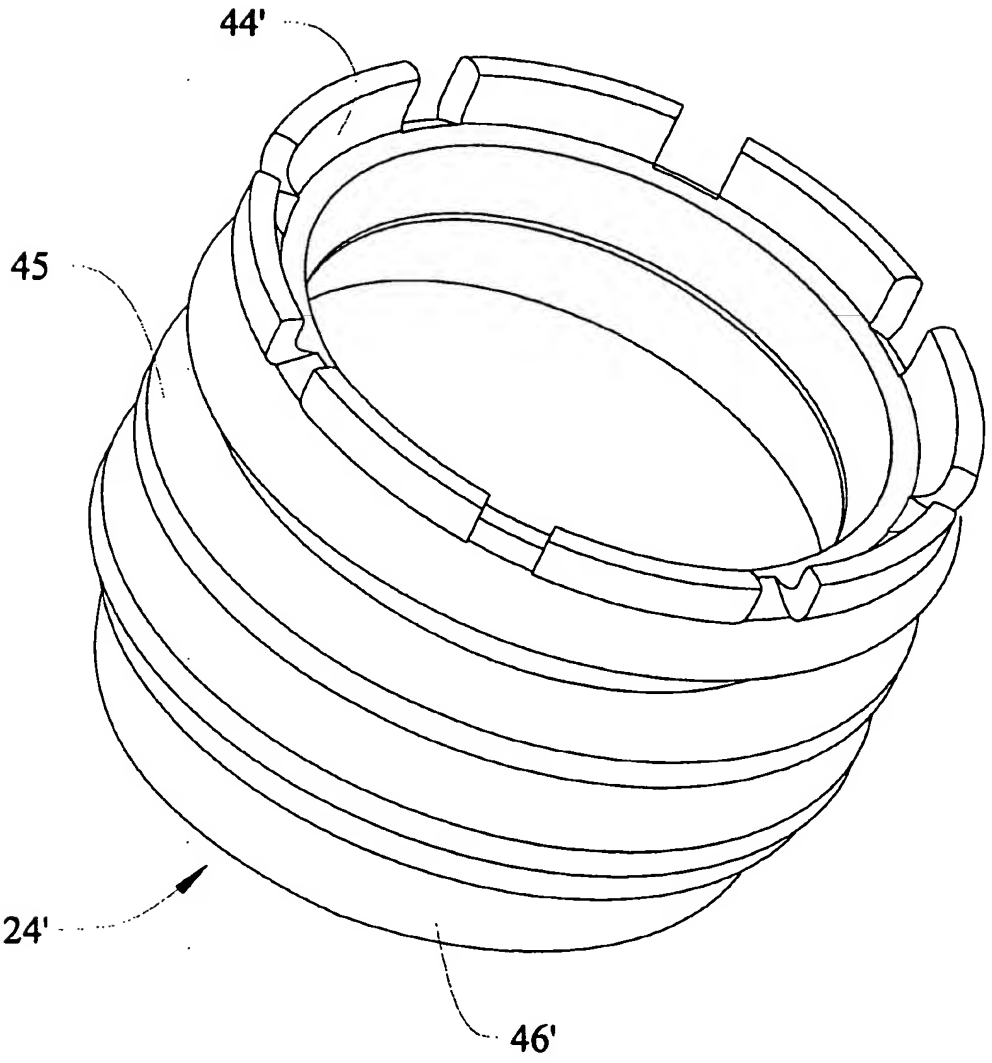
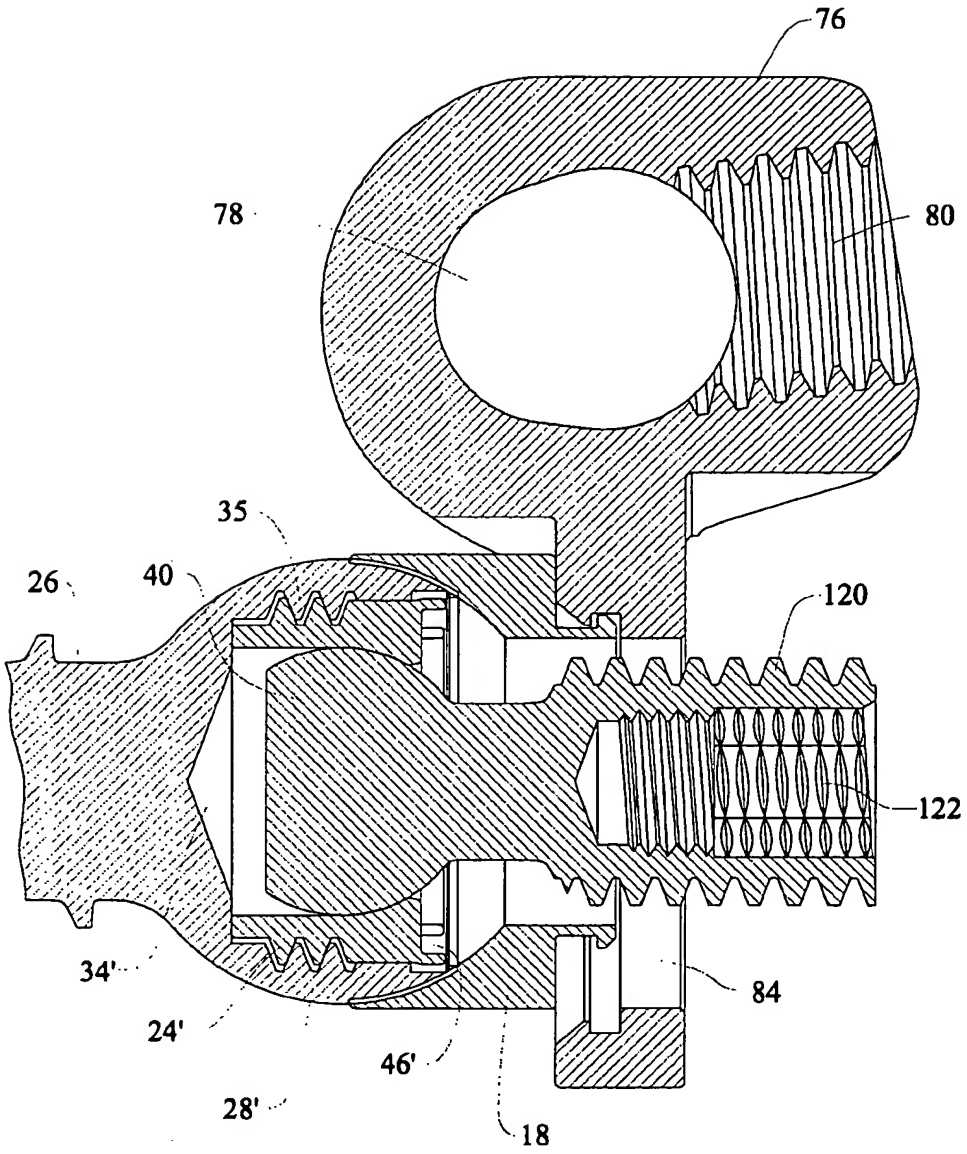


FIG. 16



SPINAL FIXATION SYSTEM

FIELD OF THE INVENTION

This invention is directed to spinal implant systems and, in particular, to a multi-component adjustable implant system capable of maintaining a desired spacial relationship among the bones of a patient's spine.

BACKGROUND OF THE INVENTION

This application provides improvements to the articulating toggle bolt bone screw disclosed in U.S. Pat. No. 5,628,740, issued to Mullane on May 13, 1997. The contents of that patent are hereby incorporated by reference.

For individuals with spinal pathologies, the development of spinal fixation devices represents a major medical breakthrough. Surgically implanted fixation systems are commonly used to correct a variety of back structure problems, including those which occur as a result of trauma or improper development during growth. These fixation systems typically include one or more stabilizing rods aligned in a desired orientation with respect to a patient's spine. Additionally, anchoring screws are inserted into the patient's spinal bones, and a series of connectors is used to rigidly link the rods and anchors.

A variety of designs exist, with each design addressing various aspects of the difficulties that arise when one reshapes an individual's spine to follow a preferred curvature. Unfortunately, known spinal implant systems often correct one set of problems only to create new ones.

Common to spinal implant systems is the necessity for proper anchoring to the bone so as to provide support for the aforementioned components. While bone screws are commonly used for anchoring, they are limited in their positioning due to the design of component pieces. Numerous patents are directed to component design in order to accommodate the bone screw, yet few patents are directed to bone screws that will accommodate existing component design. In many instances the combination of existing component design and bone screw design inhibits application to a particular spinal injury. For example, bone structure of the sacrum is typically soft, and often osteoporotic in the elderly. Perpendicular placement of a bone screw therein may not be possible and placement at an angle thereto may cause undue stress further affecting adjoining bones. Thus, if a common bone screw is employed, the component connector will be of special design.

For this and other reasons, screws located in bone structure typically use a specially designed clamp to attach to a component such as an alignment rod. A problem with specially designed clamps is th at bone structure cannot be determined until the patient's bone is exposed causing the necessity of a large inventory of various sized clamps to be o n hand during surgery, of which the surgeon must search to find the right combination. Even i f a clamp combination is predicted, insertion of the screw may still require angular insertion due to muscle or tender nerve locations. The result is a bone screw which exerts unpredictable forces upon attachment to component connectors. Further, any movement of muscle and other tissue increases the difficulty of the operation and can be a major trauma to a person.

A conventional bone screw consists of a single shaft with a coarse thread at one end for threading into the bone and a machine thread at the other end for coupling to components. Another type of bone screw has a U-shaped top which acts as a saddle for attachment to an alignment rod. If the screw is placed incorrectly for any reason, the rod clamp must be made to accommodate the position.

A number of patents exist which demonstrate the reliance on the saddle type screw support and various designs to accommodate the problem. U.S. Pat. No. 5,133,717 sets forth a sacral screw with a saddle support. Disclosed is the use of an auxiliary angled screw to provide the necessary support in placing the screw in an angular position for improved anchoring.

U.S. Pat. No. 5,129,900 sets forth an attachment screw and connector member that is adjustably fastened to an alignment rod. An oblong area provided within each connector member allows minute displacement of the alignment rod.

U.S. Pat. No. 4,887,595 discloses a screw that has a first externally threaded portion for engagement with the bone and a second externally threaded portion for engagement with a locking nut. The disclosure illustrates the use of a singular fixed shaft.

U.S. Pat. No. 4,946,458 discloses a screw which employs a spherical portion which is adapted to receive a locking pin so as to allow one portion of the screw to rotate around the spherical portion. A problem with the screw is the need for the locking pin and the inability of the base screw to accommodate a threaded extension bolt.

U.S. Pat. No. 5,002,542 discloses a screw clamp wherein two horizontally disposed sections are adapted to receive the head of a pedicle screw for use in combination with a hook which holds a support rod at an adjustable distance.

U.S. Pat. No. 4,854,304 discloses the use of a screw with a top portion that is adaptable for use with a specially designed alignment rod to permit compression as well as distraction.

U.S. Pat. No. 4,887,596 discloses a pedicle screw for use in coupling an alignment rod to the spine wherein the screw includes a clamp permitting adjustment of the angle between the alignment rod and the screw.

U.S. Pat. No. 4,836,196 discloses a screw with an upper portion design for threadingly engaging a Eemi-spherical cup for use with a specially designed alignment rod. The alignment rod having spaced apart covertures for receipt of a spherical disc allowing a support rod to be placed at angular positions.

U.S. Pat. No. 5,800,435 sets forth a modular spinal plate assembly for use with polyaxial pedicle screw implant devices. The device includes compressible components that cooperatively lock the device along included rails.

U.S. Pat. No. 5,591,166 discloses an orthopedic bone bolt and bone plate construction including a bone plate member and a collection of fasteners. At least one of the fasteners allows for multi-angle mounting configurations. The fasteners also include threaded portions configured to engage a patient's bone tissue.

U.S. Pat. No. 5,569,247 discloses a multi-angle fastener usable for connecting patient bone to other surgical implant components. The '247 device includes fastening bolts having spherical, multi-piece heads that allow for adjustment during installation of the device.

U.S. Pat. No. 5,716,357 discloses a spinal treatment and long bone fixation apparatus. The apparatus includes link members adapted to engage patient vertebrae. The link members may be attached in a chain-like fashion to connect bones in a non-linear arrangement. The apparatus also includes at least one multi-directional attachment member for joining the link members. This allows the apparatus to be used in forming a spinal implant fixation system.

Another type of spinal fixation system includes rigid screws that engage the posterior region of a patient's spine. The screws are adapted with rod-engaging free ends to engage a support rod that has been formed into a desired spine-curvature-correcting orientation. Clamping members are often used to lock the rod in place with respect to the screws. Instead of clamping members, other fixation systems, such as that disclosed in U.S. Pat. No. 5,129,900, employ connectors that join the support rods and anchoring screws. The connectors eliminate unwanted relative motion between the rod and the screws, thereby maintaining the patient's spine in a corrected orientation.

Unfortunately, although these so-called "rigid screw" fixation systems can alter the curvature of a patient's spine, they can also be difficult to install. In this type of system, the anchoring screws must be secured in a region that is strong/rigid enough to support the characteristically-large loads typically transferred from the support rods. As a result, the number of suitable anchoring locations is limited. Typically, these screws are anchored into the posterior region of a patient's spinal column or into pedicle bone. With rigid screw systems, installation requires bending a support rod into a path that will not only correct the shape a patient's spine but that will also engage each of the installed anchoring screws. Achieving a proper fit between all of the components while contending with the constraints encountered during surgery is often difficult. In severe cases, a suitable fit may not be achieved and the surgery will be unsuccessful.

Additionally, the nature of the installation process required for rigid screw fixation systems often subjects the system components to pre-loading that unduly stresses the interface between the patient's bone and the employed anchoring screws. With these designs, as a patient moves about during daily life, the system components may become separated from the supporting bone. Corrective surgery to reattach anchoring screws exposes an already-weakened region to additional trauma and presents the risk of additional damage.

Other spinal fixation systems employ adjustable components. For example, U.S. Pat. No. 5,549,608 includes anchoring screws that have pivoting free ends which attach to discrete rod-engaging couplers. As a result, the relative position of the anchoring screws and rods may be adjusted to achieve a proper fit, even after the screw has been anchored into a patient's spinal bone. This type of fixation system succeeds in easing the rod-and-screw-linking process. This adjustment capability allows the screws to accommodate several rod paths. Unfortunately, some adjustable fixation systems tolerate only limited amounts of relative adjustment between components, operating best when loaded in one of several preferred arrangements. As a result, many adjustable fixation systems provide are suitable for only a few situations.

Additionally, many adjustable fixation systems are prone to post-surgery component loosening. As a patient moves about during day-to-day living, his spine is subjected to a seemingly-endless amount of dynamic loading. Almost all activity requires some form of back motion; over time, this cyclic movement tends to work the components of many adjustable fixation systems loose.

Some adjustable spinal fixation systems include locking mechanisms designed for long-term, post-surgery securement of the system components. Although capable of being locked in place, these systems are often difficult to secure, requiring an excess of tools during the installation process. The need for extra tools, such as those required to shave or crimp key portions of a fixation system, increasing surgical risk by adding complexity and increasing the number of required steps. Although locking-component fixation systems exist, many of them unduly increase the dangers of back implant surgery to an unacceptable level.

Hardware-intensive fasteners are disclosed in U.S. Pat. No. 5,549,608, in which anchoring screws are fitted with wrenching flats that allow an anchoring screw to be attached to a patient's spinal bone with the flats being trimmed away once the screw is in place. Clamping nuts are then used to secure the anchoring screws to included stabilizing rods.

Additionally, many spinal fixation systems do not permit component repairs. If, for example, a threaded portion of a connecting member becomes stripped or cross-threaded, the entire connector must be slid off of the associated stabilizing rod. Often, such removal produces an undesirable "domino-effect," requiring that several connectors be slid off to allow removal of the damaged connector. Such requirements add unnecessary difficulty to an already-complex procedure.

Thus, what is needed is a spinal fixation system that includes the advantages of known devices, while addressing the shortcomings they exhibit. The system should allow component adjustment during installation, thereby enabling satisfactory correction of a wide variety of spinal deformities. The system should also include a component locking mechanism that is simple and reliable. The system should include two-piece connectors that may be mounted along a support rod, in-between previously-secured connectors. The system should also include mounting hardware that secures with a minimum of tools and that allows modular replacement of components damaged during installation.

SUMMARY OF THE INVENTION

The present invention is a spinal fixation system useful in reshaping the spine of a patient. The system is modular, employing a collection of anchoring assemblies that are linked, via various connectors, to strategically-arranged stabilizing rods. The stabilizing rods are shaped and aligned to impart a preferred curvature to a patient's spine.

The anchoring assemblies are multi-piece units characterized by linking members that are joined in a ball-and-socket-type arrangement with a corresponding bone-engaging member. During use, the bone-engaging member is secured to a spinal bone and the linking member is secured to one of the stabilizing rods via a corresponding connector. The bone-engaging member may include coarse, external threads or have a hook-shaped end. Each anchoring assembly also includes a support collar that provides a secure interface between the bone-engaging member and associated connector. Each anchoring assembly also includes a securing nut and a locking bolt that cooperate to prevent unwanted, post-installation motion within the anchoring assembly. The securing nut and locking bolt also prevent unwanted relative motion between the anchoring assembly and associated connector.

The connectors are rigid structures adapted to link an associated anchoring assembly with one of this stabilizing rods. In one embodiment, the connectors are two-piece constructions that allow the connector to engage a stabilizing rod in a sandwich-type arrangement, permitting connector installation and removal that does not disturb adjacent connectors.

The stabilizing rods are rigid members shaped to form a spine-curvature-correcting path. Attaching each anchoring assembly, via connectors, to a stabilizing rod forces a

patient's back into a surgeon-chosen shape. Stabilizing rods may be used singly, or in pairs, depending upon the type of correction required. The rods vary in size, but typically extend between at least two vertebrae.

Thus, it is an objective of the present invention to provide a spinal fixation system that permits component adjustment during installation, thereby enabling satisfactory correction of a wide variety of spinal deformities.

It is an additional objective of provide a spinal fixation provide a spinal fixation system that includes a component locking mechanism that is simple and reliable.

It is a further objective of the present invention to provide a spinal fixation system that includes two-piece connectors that may be mounted along, and removed from, a support rod without requiring movement of adjacent connectors.

It is yet another objective of the present invention to provide a spinal fixation system that includes mounting hardware which requires a minimum number of tools.

It is also an objective of the present invention to provide a spinal fixation system that allows modular replacement of damaged components.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a pictorial view of the spinal fixation system of the present invention;

FIG. **2** is a perspective view of an anchoring assembly used in the present spinal fixation system;

FIG. **3** is a perspective view of an anchoring assembly used in the present spinal fixation system, having a support collar removed;

FIG. **3A** is a perspective view of a support collar used in the present spinal fixation system;

FIG. **4** is a pictorial view of a bone-engaging member from an anchoring assembly of the present invention;

FIG. **4A** is a pictorial view of a linking member from an anchoring assembly of the present invention;

FIG. **4B** is a pictorial view of a retention collet of the present invention;

FIG. **5** is a pictorial view of a two-piece connector of the present invention, shown in an assembled state;

FIG. **5A** is a pictorial view of a two-piece connector main body;

FIG. **5B** is a pictorial view of a two-piece connector insertion plug;

FIG. **5C** is a pictorial view of a threaded locking insert of the present invention;

FIG. **6** is a pictorial view of a right-facing straight connector of the present invention;

FIG. **6A** is a pictorial view of the container of a left-facing straight connector of the present invention;

FIG. **7** is a pictorial view of a right-facing offset connector of the present invention;

FIG. **8** is a pictorial view of a left-facing offset connector of the present invention;

FIG. **9** is a pictorial view of the container of a hook-shaped linking member from an anchoring assembly of the present invention;

FIG. **10** is a pictorial view of a bridge connector of the present invention;

FIG. **11** is a pictorial view of a securing nut of the present invention;

FIG. **12** is a pictorial view of a locking bolt of the present invention;

FIG. **13** is a pictorial view of a rod-engaging threaded locking insert of the present invention;

FIG. **14** is a pictorial view of an alternate embodiment of an anchoring assembly and connector of the present invention;

FIG. **15** is a close-up view of an alternate embodiment of a retention collet of the present invention; and

FIG. **16** is a close-up view of the alternate anchoring assembly and connector shown in FIG. **14**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

It is to be understood that while a certain form of the invention is illustrated, it is not to be limited to the specific form or arrangement of parts herein described and shown. It will be apparent to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown in the drawings and described in the specification.

Now with reference to FIG. **1**, the spinal fixation system **10** of the present invention is shown. By way of overview, the Fixation System **10** includes a collection of bone-engaging anchoring assemblies **12** that are joined via connectors **14,14'** to stabilizing rods **16, 16'**. The specifics of the spinal fixation system **10** will now be discussed in more detail.

With additional reference to FIG. **2**, one of the included anchoring assemblies **12** is shown in an assembled state. FIG. **3** and **3A** show the anchoring assembly with an associated support collar **18** removed. In addition to the support collar **18**, each anchoring assembly **12** also includes a pedicle screw **20**, a toggle bolt **22**, and a retention collet **24**. As shown in FIG. **4**, each pedicle screw **20** includes a threaded end **26** having coarse threads sized to engage bone. Each pedicle screw **20** also includes a ball end **28** spaced apart from the threaded end **26** by a neck portion **30**. The exterior **32** of the pedicle screw ball end **28** is preferably contoured for easy grasping. The interior of the pedicle screw ball end **28** forms a retention cavity **34**, discussed below. The entrance **36** to the retention cavity **34** is characterized by a securing lip **38** that extends radially into the retention cavity **34**.

Each toggle bolt **22**, as shown in FIG. **4A**, includes a ball end **40** and an opposite threaded end **42**. As seen in FIG. **3**, the ball end **40** of the toggle bolt **22** is shaped and sized to fit inside the pedicle screw retention cavity **34**. Preferably, the interior of the retention cavity is substantially spherical, thereby matching the spherical contours of the toggle bolt ball end **40**.

With reference to FIG. **4B**, the retention collet **24** includes several wedging flanges **44** that extend from the retention collet main body **46**. As seen in FIG. **3**, the retention collet **24** is used as a bracing means to secure the ball end **40** of the toggle bolt **22** within the pedicle screw retention cavity **34**. More specifically, after the toggle bolt ball end **40** is placed within the pedicle screw retention cavity **34**, the retention collet **24** is pushed through the entrance **36** of the retention cavity **34**, until the wedging flanges **44** travel past the

engagement lip **38**, thereby bringing the retention collet main body **46** to rest against the engagement lip.

With this arrangement, the retention collet **24** allows pivotal movement of the toggle bolt **22** within the retention cavity **34**, while preventing removal of the toggle bolt therefrom. Once the retention collet **24** and toggle bolt **22** are in place, the threaded end **42** of the toggle bolt is inserted through a passthrough aperture **48** of the support collar **18**. This is shown in FIG. **2**.

Once the toggle bolt **22** has been passed through the support collar passthrough aperture **48**, the support collar **18** comes to rest against the pedicle screw ball end **28**. Although several shapes are possible, the interior of the support collar **18** preferably has a spherical contour that marches the exterior **32** of the pedicle screw ball end **28**. This arrangement limits the relative motion possible between the support collar **18** and the toggle bolt **22**, while allowing the toggle bolt ball end **40** to rotate freely within the pedicle screw retention cavity **34**. Although an assembly process has been described above, the anchoring assemblies **12** are typically delivered to the end-user surgeon as a finished unit.

In an alternate embodiment, the threaded end **26** of the pedicle screw **20** may be replaced by a hook-shaped section **50**. This hook-shaped section **50** allows the anchoring assembly **12** to be used in settings where a screw-like attachment is not appropriate, such as the fixation of bridge connectors **126**, discussed below. This hook-shaped section **50** is shown best in FIG. **9**.

The spinal fixation system **10** of the present invention includes several types of connectors **14**. More specifically, these connectors may take one of several shapes: a right-facing straight connector **52**, shown in FIG. **6**; a right-facing offset connector **54**, shown in FIG. **7**; a left-facing offset connector **56**, shown in FIG. **8**; and a left-facing straight connector **58**, shown in FIG. **6A**. Each of the various connectors **14** has a preferred use, as shown in FIG. **1**. For example, the right-facing connectors **52**, **54** are used to secure anchoring assemblies **12** to a right-side-oriented stabilizing rod **16'**. The left-facing connectors **56**, **58** are, in turn, are used to attach anchoring assemblies **12** to a left-side-oriented stabilizing rod **16**.

Additionally, each connector **14'** may be formed as a two-piece unit. With reference to FIG. **5**, a typical right-facing straight connector **52'** is shown as a two-piece unit. The two-piece connectors **14'** each include a main body **60**, shown in FIG. **5A**, and a removable locking plug **62** slidably associated therewith. More specifically, the two-piece connector main body **60** has a pair of spaced-apart engagement arms **64**. The arms **64** cooperatively fit engagement recesses **66** disposed along opposite sides of the locking plug **62**. Because the locking plug **62** of the two-piece connectors **14'** is removable, the two-piece connector is very user-friendly. If, for example, the threads within the locking insert aperture **70** become stripped or crossed during insertion of a corresponding threaded locking insert **68**, the locking plug **62** may be replaced merely by sliding the locking plug laterally out from between the attachment flanges **72** associated with the connector main body **60**. As a result, the entire connector **14'** need not be replaced. This reduces possible additional trauma that may otherwise be induced if the entire connector needed to be replaced. A threaded locking insert **68** is shown in FIG. **5C**.

The two-piece connector **14'** is especially useful as a connector that may be installed once other connectors **14** have already been locked in place. The removable nature of the locking plug **62** allows the connector main body **60** to be attached to a stabilizing rod **16**, **16'** without the need to slide the connector **14'** along the length of the rod. Instead, the main body **60** is secured to an appropriate anchoring assembly **12** and the engagement arms **64** are arranged to straddle an intended attachment location along the rod **16**, **16'**. The locking plug **62** is then slid into place between the engagement arms **64**. As with the one piece connectors **14**, the two-piece connectors **14'** are locked into place with respect to a stabilizing rod **16**, **16'** via a threaded locking insert **68**, screwed into a locking insert aperture **70** and tightened against the corresponding stabilizing rod **16**, **16'**.

The two-piece connectors **14'** each include an attachment flange **72** extending from the main body **60**. The two-piece connector attachment flange **72** includes a passthrough aperture **74** sized to accommodate the threaded end **42** of the toggle bolt **22** associated with a corresponding anchoring assembly **12**.

As seen in FIG. **6**, each right-facing straight connector **52** includes a main body **76** characterized by a rod bore **78** and a threaded locking insert aperture **80**. An attachment flange **82** extends orthogonally from the main body **76** of each right-facing straight connector **52**. The attachment flange **82** includes a passthrough aperture **84**. Preferably, the passthrough aperture **84** is oblong and sized to accommodate the threaded end **42** of a toggle bolt **22** associated with a corresponding anchoring assembly **12**. As seen in FIG. **1**, the rod bore **78** is sized to allow passage there through the right-side stabilizing rod **16'**. A threaded locking insert **68** is used to secure the right-facing straight connector **52** to the rod **16'**. More specifically, the exterior of the locking insert **68** is threaded to engage the locking insert aperture **80** located within the right-facing straight connector main body **76**.

As seen in FIG. **7**, each right-facing offset connector **54** includes a main body **86** characterized by a rod bore **88** and a threaded locking insert aperture **90**. An attachment flange **92** extends orthogonally from the main body **86** of each right-facing offset connector **54**. The attachment flange **92** includes a passthrough aperture **94**. Preferably, the passthrough aperture **94** is oblong and sized to accommodate the thareaded end **42** of a toggle bolt **22** associated with a corresponding anchoring assembly **12**. As seen in FIG. **1**, the rod bore **88** is sized to allow passage there through the right-side stabilizing rod **16'**. A threaded locking insert **78** is used to secure the right-facing offset connector **54** to the rod **16'**. More specifically, the exterior of the locking insert **78** is threaded to engage the locking insert aperture **90** located within the right-facing offset connector main body **86**.

As seen in FIG. **8**, each left-facing offset connector **56** includes a main body **96** characterized by a rod bore **98** and a threaded locking insert aperture **100**. An attachment flange **102** extends orthogonally from the main body **96** of each left-facing offset connector **56**. The attachment flange **102** includes a passthrough aperture **104**. Preferably, the passthrough aperture **104** is oblong and sized to accommodate the threaded end **42** of a toggle bolt **22** associated with a corresponding anchoring assembly **12**. As seen in FIG. **1**, the rod bore **98** is sized to allow passage there through the left-side stabilizing rod **16**. A threaded locking insert **68** is used to secure the left-facing offset connector **56** to the rod **16**. More specifically, the exterior of the locking insert **68** is threaded to engage the locking insert aperture **100** located within the left-facing offset connector main body **96**.

As seen in FIG. **6A**, each left-facing straight connector **58** includes a main body **106** characterized by a rod bore **108** and a threaded locking insert aperture **110**. An attachment

flange 112 extends orthogonally from the main body 106 of each left-facing straight connector 58. The attachment flange 112 includes a passthrough aperture 114. Preferably, the passthrough aperture 114 is oblong and sized to accommodate the threaded end 42 of a toggle bolt 22 associated with a corresponding anchoring assembly 12. As seen in FIG. 1, the rod bore 108 is sized to allow passage there through the left-side stabilizing rod 16. A threaded locking insert 68 is used to secure the left-facing straight connector 56 to the rod 16. more specifically, the exterior of the locking insert 68 is threaded to engage the locking insert aperture 110 located within the left-facing straight connector main body 96.

Each of the one-piece connectors 14 and two-piece connectors 14' is joined to one of the anchoring assemblies 12 a securing nut 116 and a locking bolt 118. With reference FIG. 4A, the toggle bolt threaded end 42 has exterior threads 120 and a threaded interior bore or locking bolt cavity 122. The exterior threads 120 follow a right handed thread pattern and correspond with the threads of the securing nut 116. However, the threaded interior bore 122 of the toggle bolt threaded end 42 has threads that follow a left handed pattern. The locking bolt 118, which has a left-handed thread pattern as well, screws into the threaded bolt cavity 122.

With this arrangement, an anchoring assembly 12 may be joined, for example, to a right-facing straight connector 52 as follows: A corresponding toggle bolt threaded end 42 is inserted through the passthrough aperture 84 of the connector attachment flange 82. The toggle bolt 22 is held in place by tightening a securing nut 116 downward along the toggle bolt exterior threads 120.

With additional reference to FIG. 3, the threaded interior bore 122 of the toggle bolt threaded end 42 has a hexagonal cross section. This allows the insertion of an allen wrench, not shown, into the interior bore 122 to prevent relative motion between the spherical ball end 40 of the toggle bolts 22 and the spherical retention cavity 34 of the pedicle screw 20. The inserted allen wrench thereby prevents unwanted spinning of the toggle bolt 22 within the retention cavity 34 while the securing nut 116 is tightened onto the exterior threads 120.

Tightening the securing nut 116 forces the toggle bolt threaded end 42 to travel longitudinally through the passthrough aperture 84 and also causes the toggle bolt ball end 40 to be forced against the retention collet wedging flanges 44. Further tightening of the securing nut 116 forms a substantially rigid fit between the toggle bolt 22 and the pedicle screw 20. With the securing nut 116 tightened appropriately, the toggle bolt threaded end 42 is locked in place with regard to the right-facing straight connector attachment flange 82, and the toggle bolt ball end 40 is locked in place within the pedicle screw retention cavity 34. In this state, the retention collet wedging flanges 44 are sandwiched between the exterior of the toggle bolt ball end 40 and the interior of the retention cavity 34. Since the retention collet 34 is locked within the retention cavity 34 by the retention cavity engagement lip 38, relative motion between the toggle bolt ball end and the pedicle screw 20 is prevented once the toggle bolt threaded end 42 is locked in place by the tightened securing nut 116. This results in a rigid link between the right-facing straight connector 52 and the anchoring assembly 12.

Although the above description refers to joining an anchoring assembly 12 specifically to a right-facing straight connector 52, each of the one-piece connectors 14 and two-piece connectors 14' may be attached to an anchoring assembly in a similar manner. That is, right-facing offset connectors 54 are attached by inserting a toggle bolt threaded end 42 through the associated passthrough aperture 94; left-facing offset connectors 56 are joined with an anchoring assembly by inserting a toggle bolt threaded end through an associated passthrough aperture 104; and left-facing straight connectors 58 are attached to anchoring assemblies by inserting a toggle bolt threaded end through an associated passthrough aperture 114. In each case, the exterior threads 120 of the inserted toggle bolt threaded end 42 are held in place by a tightened securing nut 116, as described previously.

To prevent unwanted loosening of a connector 14, 14' and anchoring assembly 12 union, a locking bolt 118 is inserted into the threaded interior bore 122 of the toggle bolt 22 corresponding to each anchoring assembly that has been secured in place. As mentioned above, each locking bolt 118 has a left-handed thread pattern, thereby matching the left-handed thread pattern of each toggle bolt threaded interior bore 122. The locking bolt 118 is screwed into an associated toggle bolt threaded interior bore 122 until the locking bolt head plate 124 comes to rest against the securing nut 116 that holds the corresponding anchoring assembly 12 in places with respect to the associated connector 14, 14'. Incorporating this locking bolt 118 ensures that anchoring assemblies 12 and connectors 14, 14' stay locked in place, thereby preventing unwanted relative motion within the spinal fixation system 10.

Now with reference to FIG. 14, an alternate embodiment of an anchoring assembly 12' is shown secured to a right-facing straight connector 52. In this embodiment, a alternate retention collet 24' is used to secure the toggle bolt ball end 40 within a securing cavity 34' disposed within the ball end 28 of an associated pedicle screw 20'. Relative position between the pedicle screw 20 and the connector 52 is maintained by an associated support collar 18. The support collar 18 is disposed between the pedicle screw ball end 28' and the attachment flange 82 of the connector 52.

With reference to FIG. 15, a close-up view of an alternate embodiment of the retention collet 24' is shown. The exterior surface of the collet 24' is characterized by external threads 45. With additional reference to FIG. 16, the collet external threads 45 are shaped to engage internal threads 35 disposed within the retention cavity 34. Additionally, the retention collet 24' includes wedging flanges 44' shaped and sized to engage the exterior surface of an associated toggle bolt ball end 40.

The spinal fixation system 10 is preferably formed from rigid, biocompatible materials. One such preferred material is titanium; however, other materials may be used as well.

The bridge connector 126 shown in FIG. 10 is used to provide additional support along the stabilizing rods 16, 16', as shown in FIG. 1. With reference to FIG. 10, the bridge connector 126 includes passthrough apertures 128, located at opposite ends 130,132 of the connector. Typically, the bridge connector 126 is held in place with an anchoring assembly 12 that includes a hook-shaped section 50, shown in FIG. 9. Each bridge connector end 130, 132 is secured to a corresponding stabilizing rod 16, 16' by inserting the threaded end 42 of a toggle bolt 22 through the bridge connector passthrough apertures 128. The toggle bolt 22 is held in place with a securing nut 116 and a locking bolt 118. This prevents unwanted motion of the bridge connector 126 and ensures proper spacing between the stabilizing rods 16, 16'. The bridge connectors 126, themselves, are attached to stabilizing rods 16,16' via a bridge attachment member 127, shown in FIG. 13. Each bridge attachment member 127

includes an engagement neck **129** sized for insertion into a bridge connector passthrough aperture **129**. The engagement neck **129** includes external threads **131** and internal threads **133**, with the threads pitched to accommodate the previously described securing nuts **116** and locking bolts **118**. Each bridge attachment member **127** is further characterized by a rod engagement cavity **134** shaped to engage the outer contours of a corresponding stabilizing rod **16,16'**.

Although the invention has been described in terms of a specific embodiment, it will be readily apparent to those skilled in this art that various modifications, rearrangements and substitutions can be made without departing from the spirit of the invention. The scope of the invention is defined by the claims appended hereto.

What is claimed is:

1. An anchoring assembly comprising:

a linking member having a threaded first end and a substantially-spherical second end;

a bone-engaging member having a first end adapted to engage said bone and a second end comprising a retention cavity constructed and arranged to engage said linking member second end, said retention cavity having a substantially-spherical exterior surface;

a bracing means for selectively maintaining said linking member second end in a chosen orientation within said retention cavity;

a support collar adapted for placement against said bone-engaging member second end, said collar having a contoured surface sized and shaped to adjustably engage said exterior surface of said bone-engaging member second end;

whereby said bracing means selectively prevents relative motion between said linking member and said bone-engaging member.

2. The anchoring assembly of claim **1**, wherein said bracing means includes:

a securing nut mounted on said threaded first end of said linking member;

a retention collet mounted within an entrance to said retention cavity, said retention collet comprising a main body having a substantially-circular cross section and a plurality of wedging flanges that extend from said main body, the diameter of said circular cross section being smaller than the diameter of said linking member spherical second end, whereby said retention collet prevents removal of said linking member second end from within said retention cavity, and whereby tightening said securing nut draws said linking member second end against said wedging flanges, thereby preventing motion of said linking member with respect to said bone-engaging member.

3. The anchoring assembly of claim **2**, wherein said anchoring assembly is adapted for use with at least one connector adapted to selectively engage at least one stabilizing element, said anchoring assembly further including:

a locking means for attaching said linking member second end to said connector, said locking means including a securing nut adapted to engage an exterior of said linking member second threaded first end; and a locking bolt adapted to engage internal threads located within a bolt cavity longitudinally disposed within said linking member second end;

whereby said securing nut maintains said linking member second end in place when said second end extends through a passthrough aperture, of said connection and whereby a locking bolt prevents unwanted relative motion between said securing nut and said linking member.

4. The anchoring assembly of claim **3**, wherein:

said exterior of said linking member first end forms a helix having a first pitch and said internal threads within said bolt cavity form a helix having a second pitch, said second pitch being opposite said first pitch.

5. A spinal fixation system comprising:

at least one stabilizing rod;

a plurality of connectors adapted to selectively engage said at least one stabilizing rod;

a plurality of anchoring assemblies each adapted to secure one of said connectors to a spinal bone of an individual, each of said anchoring assemblies including a linking member having a threaded first end and a substantially-spherical second end, said threaded first end being sized to engage one of said connectors; and a bone-engaging member having a first end adapted to engage said bone and a second end comprising a retention cavity constructed and arranged to engage said linking member second end, said retention cavity having a substantially-spherical exterior surface;

a locking means for attaching said linking member second end to one of said connectors;

a bracing means for selectively maintaining said linking member second end in a chosen orientation within said retention cavity;

a support collar adapted for placement between said bone-engaging member second end and one of said connectors; said collar having a contoured first surface sized and shaped to adjustably engage said exterior surface of said bone-engaging member second end, and a second surface sized and shaped to abut one of said connectors;

whereby said support collar provides a force distributing interface that transfers loads uniformly between said anchoring assembly and one of said connectors regardless of orientation of said linking member relative to said bone-engaging member, thereby allowing adjustable securement of said anchoring assembly to one of said connectors; and whereby said bracing means prevents relative motion between said anchoring assembly and said corresponding connector once said anchoring assembly and said corresponding connector have been arranged in a spinal-curve-correcting orientation.

6. The spinal fixation system of claim **5**, wherein each of said connectors includes:

a rod-engaging bore adapted to accept one of said stabilizing rods;

a passthrough aperture oriented transverse to said rod-engaging bore, said passthrough aperture being sized to accommodate said linking member first end; and a threaded insert adjustably disposed within a locking insert aperture spanning between an exterior surface of said connector to said rod-engaging bore, whereby said threaded insert adjustably locks said connector to one of said stabilizing rods inserted through said rod-engaging bore.

7. The spinal fixation system of claim **6**, wherein at least one of said connectors is a two-piece assembly comprising a main body and a locking plug removably attached thereto, said locking insert aperture being disposed within said locking plug, and said passthrough aperture being disposed with said main body.

8. The spinal fixation system of claim 5, wherein said locking means includes:

a securing nut adapted to engage an exterior of said linking member threaded first end; and

a locking bolt adapted to engage internal threads located within a bolt cavity longitudinally disposed within said linking member second end;

whereby said securing nut maintains said linking member second end in place when said second end extends through said passthrough aperture, and whereby said locking bolt prevents unwanted relative motion between said securing nut and said linking member.

9. The spinal fixation system of claim 8, wherein said exterior of said linking member first end forms a helix having a first pitch and said internal threads within said bolt cavity form a helix having a second pitch, said second pitch being opposite said first pitch.

10. The spinal fixation system of claim 8, wherein said bolt cavity of said linking member second end has a substantially-hexagonal cross section.

11. The spinal fixation system of claim 8, wherein said bracing means includes a retention collet mounted within an entrance to said retention cavity, said retention collet comprising a main body having an essentially-circular cross section and a plurality of wedging flanges that extend from said main body, the diameter of said circular cross section being smaller than the diameter of said linking member spherical second end, whereby said retention collet prevents removal of said linking member second end from within said retention cavity, and whereby tightening said securing nut draws said linking member second end against said wedging flanges, thereby preventing motion of said linking member with respect to said bone-engaging member.

12. The spinal fixation system of claim 5, wherein said bone-engaging member is a screw having threads adapted to engage a spinal bone of said patient.

13. The spinal fixation system of claim 5, wherein said bone-engaging member is hooked shaped.

14. A spinal fixation system for use with at least one spine stabilizing rods, said system comprising:

a plurality of connectors adapted to selectively engage said at least one stabilizing rod;

a plurality of anchoring assemblies each adapted to secure one of said connectors to a spinal bone of an individual, each of said anchoring assemblies including a linking member having a threaded first end and a substantially-spherical second end, said threaded first end being sized to engage one of said connectors; and a bone-engaging member having a first end adapted to engage said bone and a second end comprising a retention cavity constructed and arranged to engage said linking member second end, said retention cavity having a substantially-spherical exterior surface;

a locking means for attaching said linking member second end to one of said connectors;

a bracing means for selectively maintaining said linking member second end in a chosen orientation within said retention cavity;

a support collar adapted for placement between said bone-engaging member second end and one of said connectors; said collar having a contoured first surface sized and shaped to adjustably engage said exterior surface of said bone-engaging member second end, and a second surface sized and shaped to abut one of said connectors;

whereby said support collar provides a force distributing interface that transfers loads uniformly between said anchoring assembly and one of said connectors regardless of orientation of said linking member relative to said bone-engaging member, thereby allowing adjustable securement of said anchoring assembly to one of said connectors; and whereby said bracing means prevents relative motion between said anchoring assembly and said corresponding connector once said anchoring assembly and said corresponding connector have been arranged in a spinal-curve-correcting orientation.

15. The spinal fixation system of claim 14, wherein each of said connectors includes:

a rod-engaging bore adapted to accept one of said stabilizing rods;

a passthrough aperture oriented transverse to said rod-engaging bore, said passthrough aperture being sized to accommodate said linking member first end; and a threaded insert adjustably disposed within a locking insert aperture spanning between an exterior surface of said connector to said rod-engaging bore, whereby said threaded insert adjustably locks said connector to one of said stabilizing rods inserted through said rod-engaging bore.

16. The spinal fixation system of claim 15, wherein at least one of said connectors is a two-piece assembly comprising a main body and a locking plug removably attached thereto, said locking insert aperture being disposed within said locking plug, and said passthrough aperture being disposed with said main body.

17. The spinal fixation system of claim 14, wherein said locking means includes:

a securing nut adapted to engage an exterior of said linking member threaded first end; and

a locking bolt adapted to engage internal threads located within a bolt cavity longitudinally disposed within said linking member second end;

whereby said securing nut maintains said linking member second end in place when said second end extends through said passthrough aperture, and whereby said locking bolt prevents unwanted relative motion between said securing nut and said linking member.

18. The spinal fixation system of claim 17, wherein said exterior of said linking member first end forms a helix having a first pitch and said internal threads within said bolt cavity form a helix having a second pitch, said second pitch being opposite said first pitch.

19. The spinal fixation system of claim 17, wherein said bolt cavity of said linking member second end has a substantially-hexagonal cross section.

20. The spinal fixation system of claim 17, wherein said bracing means includes a retention collet mounted within an entrance to said retention cavity, said retention collet comprising a main body having an essentially-circular cross section and a plurality of wedging flanges that extend from said main body, the diameter of said circular cross section being smaller than the diameter of said linking member spherical second end, whereby said retention collet prevents removal of said linking member second end from within said retention cavity, and whereby tightening said securing nut draws said linking member second end against said wedging flanges, thereby preventing motion of said linking member with respect to said bone-engaging member.

21. An anchoring assembly for use with a spinal fixation system, said spinal fixation system including at least one spine stabilizing rod and at least one connector adapted to selectively engage said at least one stabilizing rod, said anchoring assembly comprising:

a linking member having a threaded first end and a substantially-spherical second end, said threaded first end being sized to engage said connector;

a bone-engaging member having a first end adapted to engage said bone and a second end comprising a retention cavity constructed and arranged to engage said linking member second end, said retention cavity having a substantially-spherical exterior surface;

a locking means for attaching said linking member second end to said connector;

a bracing means for selectively maintaining said linking member second end in a chosen orientation within said retention cavity;

a support collar adapted for placement between said bone-engaging member second end and said connector, said collar having a contoured surface sized and shaped to adjustably engage said exterior surface of said bone-engaging member second end, and a second surface sized and shaped to abut said connector;

whereby said support collar provides a force distributing interface that transfers loads uniformly between said anchoring assembly and said connector regardless of orientation of said linking member relative to said bone-engaging member, thereby allowing adjustable securement of said anchoring assembly to said connector; and whereby said bracing means prevents relative motion between said anchoring assembly and said connector once said anchoring assembly and said connector have been arranged in a spinal-curve-correcting orientation.

22. The anchoring assembly of claim **21**, wherein said locking means includes:

a securing nut adapted to engage an exterior of said linking member threaded first end; and

a locking bolt adapted to engage internal threads located within a bolt cavity longitudinally disposed within said linking member second end;

whereby said securing nut maintains said linking member second end in place when said second end extends through said passthrough aperture, and whereby said locking bolt prevents unwanted relative motion between said securing nut and said linking member.

23. The anchoring assembly of claim **22**, wherein said bracing means includes:

a retention collet mounted within an entrance to said retention cavity, said retention collet being comprising a main body having a substantially-circular cross section and a plurality of wedging flanges that extend from said main body, the diameter of said circular cross section being smaller than the diameter of said linking member spherical second end, whereby said retention collet prevents removal of said linking member second end from within said retention cavity, and whereby tightening said securing nut draws said linking member second end against said wedging flanges, thereby preventing motion of said linking member with respect to said bone-engaging member.

24. The anchoring assembly of claim **22**, wherein:

said exterior of said linking member first end forms a helix having a first pitch and said internal threads within said bolt cavity form a helix having a second pitch, said second pitch being opposite said first pitch.

25. The anchoring assembly of claim **22**, further including

a plurality of said locking means having a plurality of securing nuts and locking bolts;

a bridge connector adapted to span between two of said stabilizing rods; and

a plurality of connector attachment members each adapted to selectively secure one end of said bridge connector to a corresponding one of said rods; said connector attachment members having an engagement neck adapted to engage one of said securing nuts and one of said locking bolts; said bridge connectors having a rod engaging cavity adapted to engage the exterior of a corresponding one of said rods;

whereby said bridge connectors and said connector attachment members cooperatively maintain said rods in a spaced apart relationship, and whereby said securing nuts and said locking bolts cooperatively maintain said connector attachment members in a selectively fixed relationship.

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(54) **SPLIT RING BONE SCREW FOR A SPINAL FIXATION SYSTEM**

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(58) **Field of Search** 606/61, 71, 73, 606/60, 69, 70, 72

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5,129,900 A		7/1992	Asher et al.	
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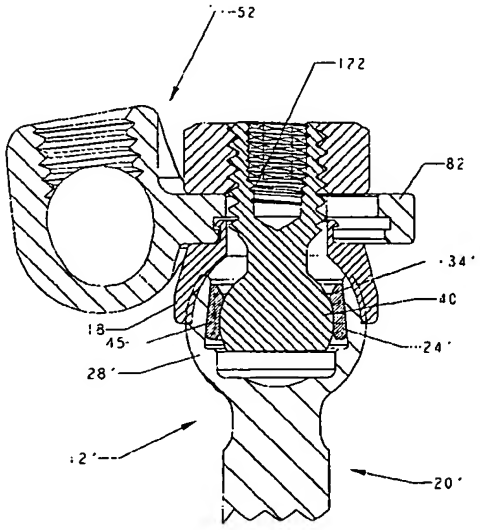
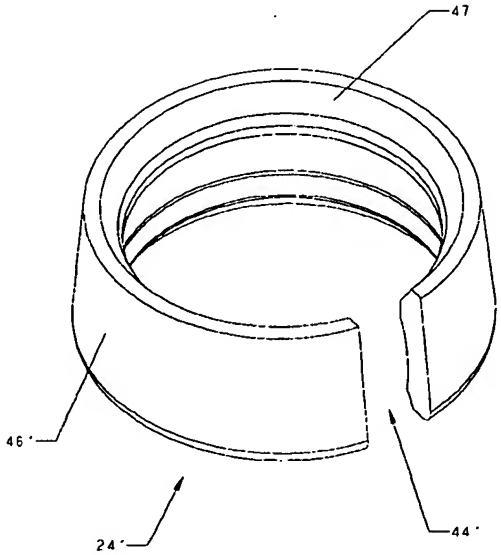
Assistant Examiner—David A Bonderer
(74) *Attorney, Agent, or Firm*—McHale & Slavin, P.A.

(57) **ABSTRACT**

An adjustable spinal fixation system is composed of a collection of anchoring assemblies attached, via a variety of connectors, to spine-stabilizing rods. The anchoring assemblies include a linking member attached in a ball-and-socket fashion to a bone-engaging member that is adapted to engage a spinal bone of a patient. The linking member joins one of the included connectors to an associated bone-engaging member. The connectors are selectively attached to one of the stabilizing rods. The anchoring assemblies each include a support collar and a split retention ring that cooperate to allow adjustment of the bone-engaging member and corresponding connector during surgery. When surgery is complete, a securing nut and locking bolt cooperate with the support collar and split retention ring to maintain the relative position of the entire fixation system, preventing unwanted movement between the system components.

2 Claims, 5 Drawing Sheets





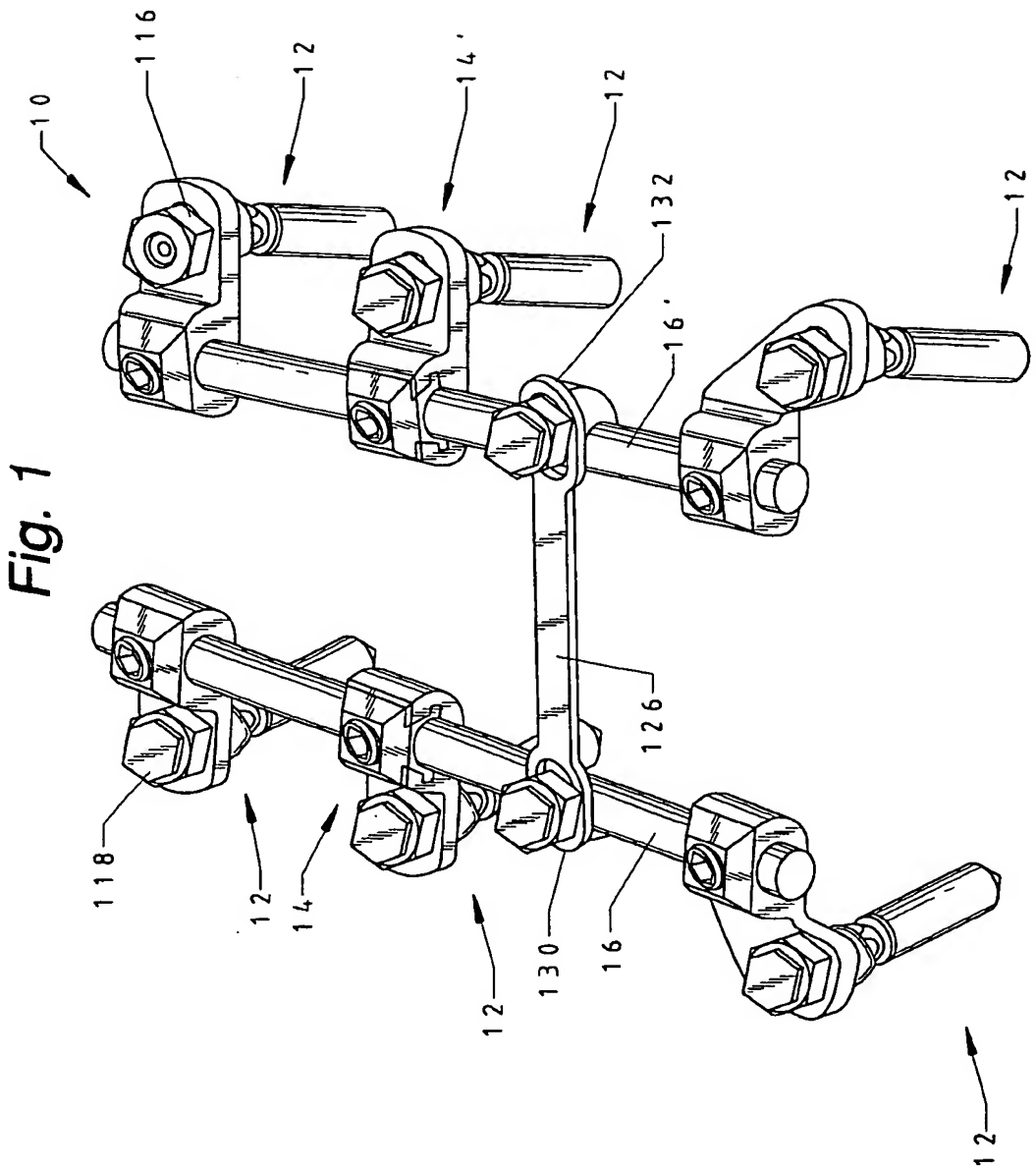
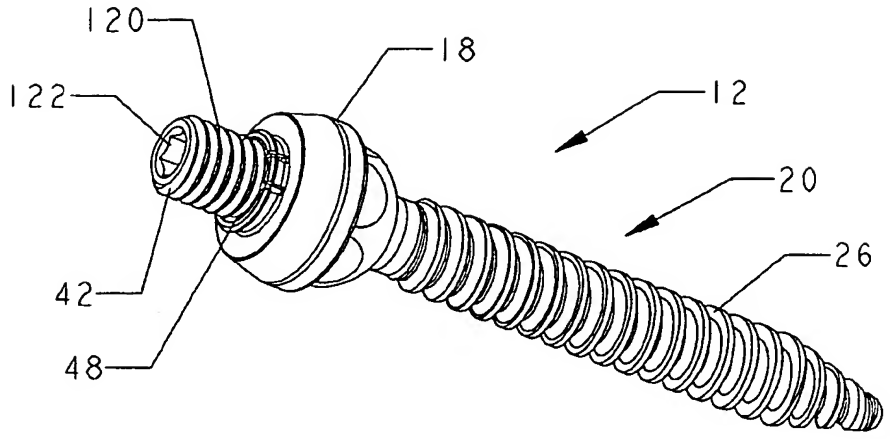


Fig. 1

Fig. 2



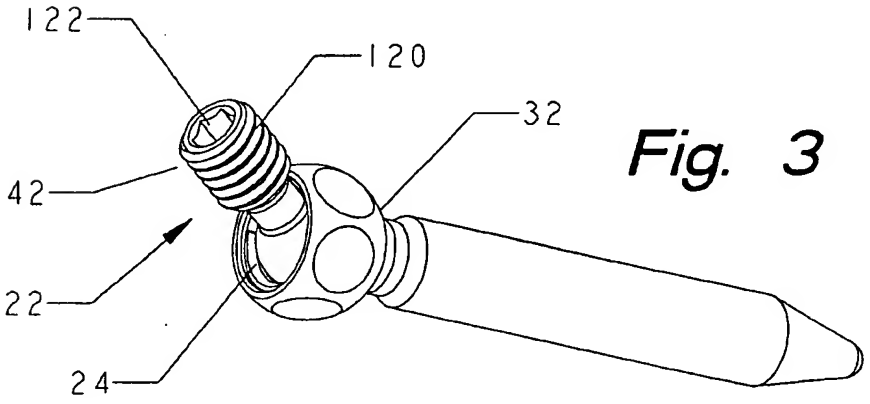


Fig. 3

Fig. 3A

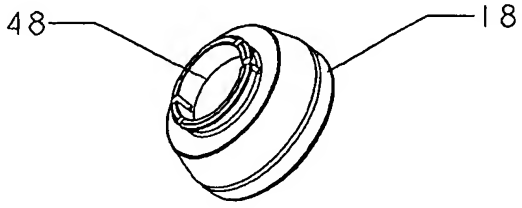
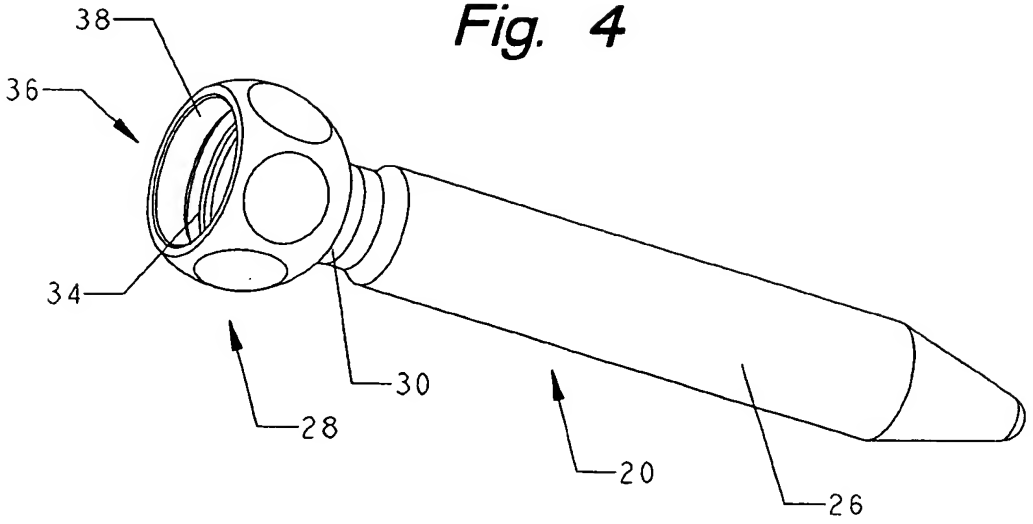


Fig. 4



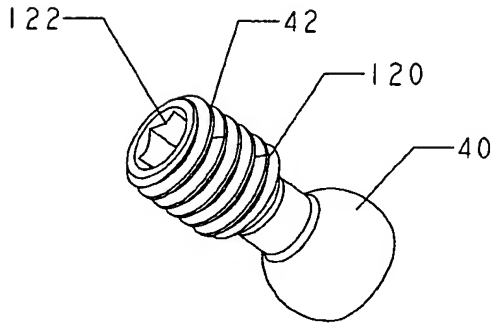


Fig. 4A

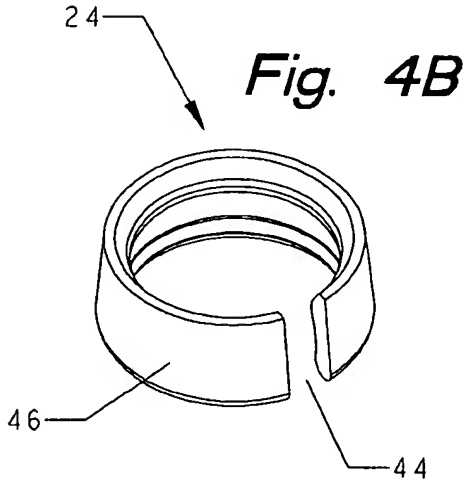


Fig. 4B

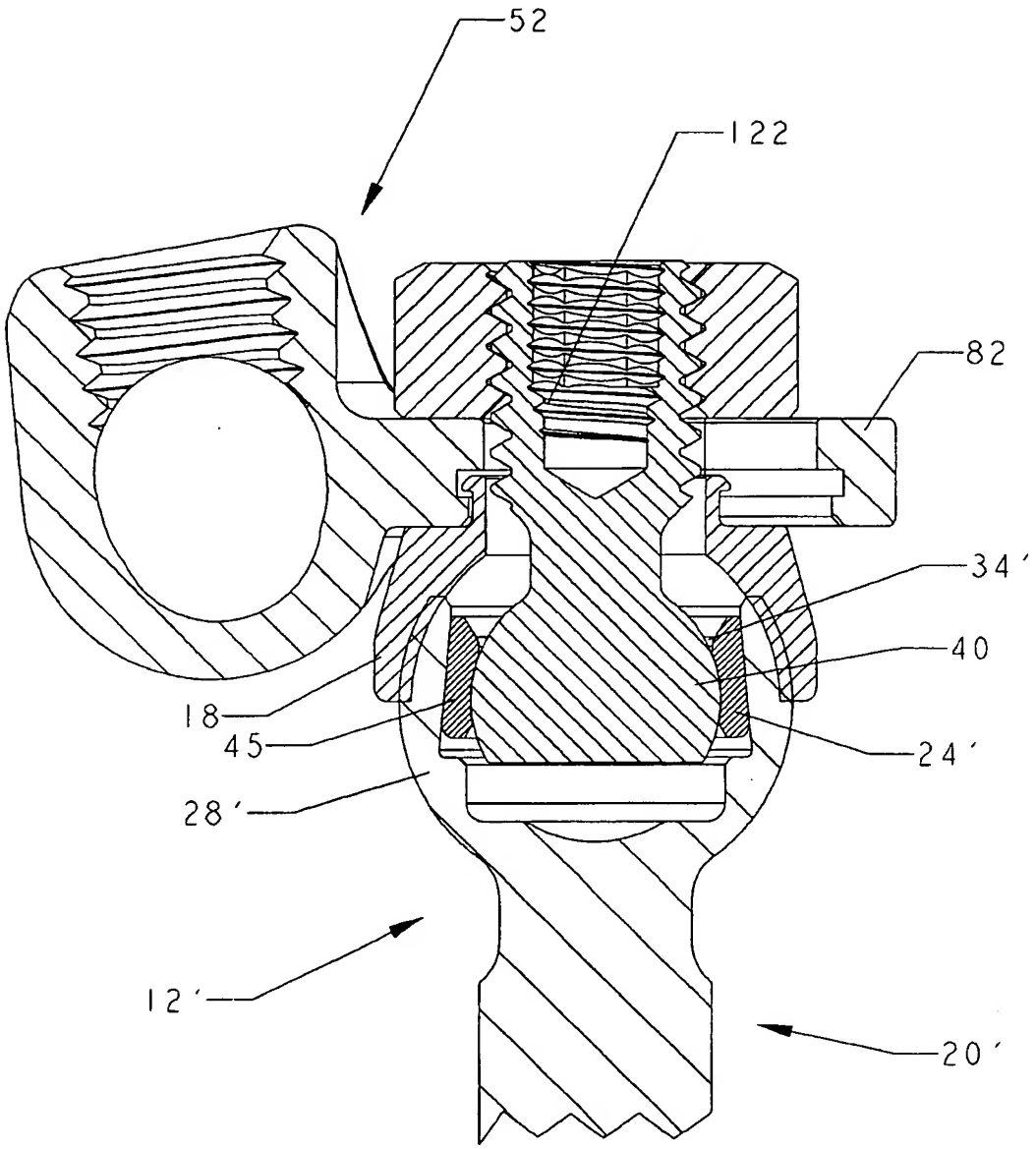


Fig. 5

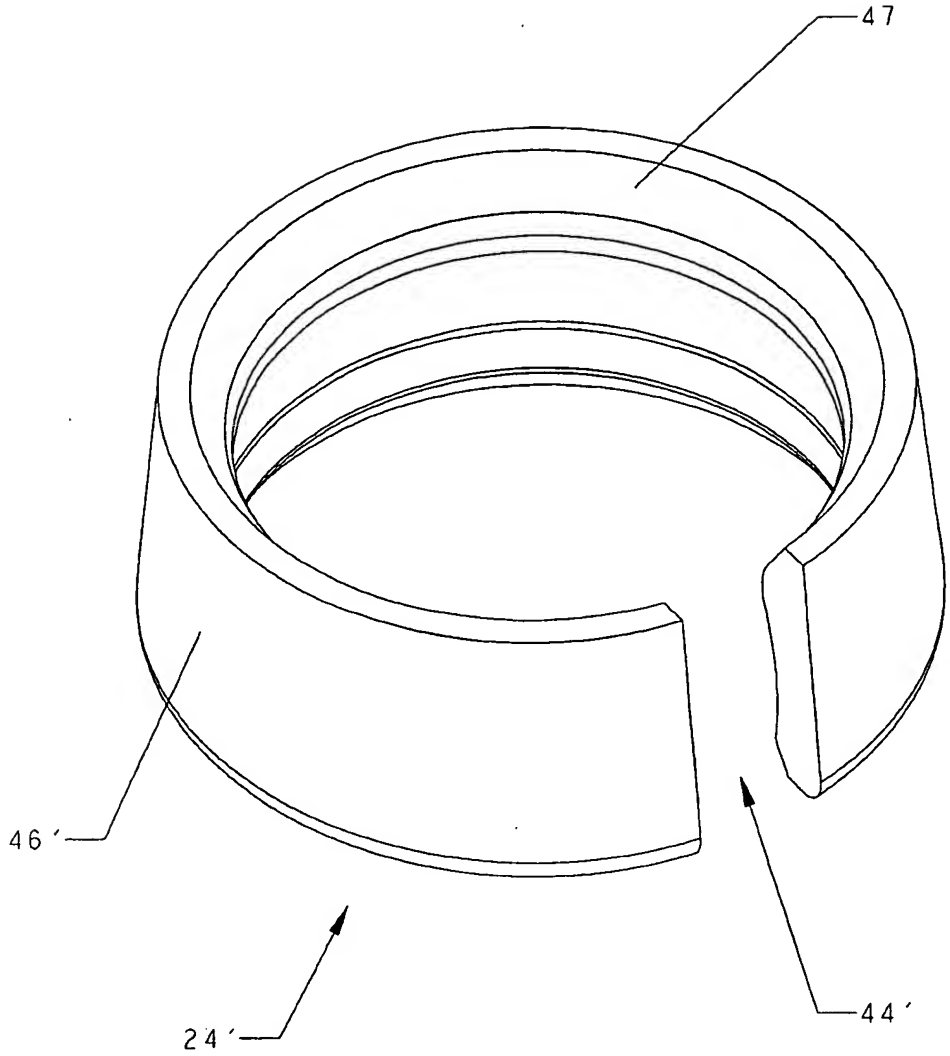


Fig. 6

SPLIT RING BONE SCREW FOR A SPINAL FIXATION SYSTEM

This application is related to an application, entitled Split Sleeve Locking Modular Hip, Ser. No. 09/982,448, by the same inventors, filed on even date herewith.

FIELD OF THE INVENTION

This invention is directed to spinal implant systems and, in particular, to a multi-component adjustable implant system capable of maintaining a desired spacial relationship among the bones of a patient's spine.

BACKGROUND OF THE INVENTION

This application provides improvements to the articulating toggle bolt bone screw disclosed in U.S. Pat. No. 5,628,740, issued to Mullane on May 13, 1997 and U.S. Pat. No. 6,050,997 issued to Mullane on Apr. 18, 2000. The contents of those patents are hereby incorporated by reference.

For individuals with spinal pathologies, the development of spinal fixation devices represents a major medical breakthrough. Surgically implanted fixation systems are commonly used to correct a variety of back structure problems, including those which occur as a result of trauma or improper development during growth. These fixation systems typically include one or more stabilizing rods aligned in a desired orientation with respect to a patient's spine. Additionally, anchoring screws are inserted into the patient's spinal bones, and a series of connectors is used to rigidly link the rods and anchors.

A variety of designs exist, with each design addressing various aspects of the difficulties that arise when one re-shapes an individual's spine to follow a preferred curvature. Unfortunately, known spinal implant systems often correct one set of problems only to create new ones.

Common to spinal implant systems is the necessity for proper anchoring to the bone so as to provide support for the aforementioned components. While bone screws are commonly used for anchoring, they are limited in their positioning due to the design of component pieces. Numerous patents are directed to component design in order to accommodate the bone screw, yet few patents are directed to bone screws that will accommodate existing component design. In many instances the combination of existing component design and bone screw design inhibits application to a particular spinal injury. For example, bone structure of the sacrum is typically soft, and often osteoporotic in the elderly. Perpendicular placement of a bone screw therein may not be possible and placement at an angle thereto may cause undue stress further affecting adjoining bones. Thus, if a common bone screw is employed, the component connector will be of special design.

For this and other reasons, screws located in bone structure typically use a specially designed clamp to attach to a component, such as an alignment rod. A problem with specially designed clamps is that bone structure cannot be determined until the patient's bone is exposed causing the necessity of a large inventory of various sized clamps to be on hand during surgery, of which the surgeon must search to find the right combination. Even if a clamp combination is predicted, insertion of the screw may still require angular insertion due to muscle or tender nerve locations. The result is a bone screw which exerts unpredictable forces upon attachment to component connectors. Further, any movement of muscle and other tissue increases the difficulty of the operation and can be a major trauma to a person.

A conventional bone screw consists of a single shaft with a coarse thread at one end for threading into the bone and a machine thread at the other end for coupling to components. Another type of bone screw has a U-shaped top which acts as a saddle for attachment to an alignment rod. If the screw is placed incorrectly for any reason, the rod clamp must be made to accommodate the position.

A number of patents exist which demonstrate the reliance on the saddle type screw support and various designs to accommodate the problem.

U.S. Pat. No. 5,133,717 sets forth a sacral screw with a saddle support. Disclosed is the use of an auxiliary angled screw to provide the necessary support in placing the screw in an angular position for improved anchoring.

U.S. Pat. No. 5,129,900 sets forth an attachment screw and connector member that is adjustably fastened to an alignment rod. An oblong area provided within each connector member allows minute displacement of the alignment rod.

U.S. Pat. No. 4,887,595 discloses a screw that has a first externally threaded portion for engagement with the bone and a second externally threaded portion for engagement with a locking,nut. The disclosure illustrates the use of a singular fixed shaft.

U.S. Pat. No. 4,946,458 discloses a screw which employs a spherical portion which is adapted to receive a locking pin so as to allow one portion of the screw to rotate around the spherical portion. A problem with the screw is the need for the locking pin and the inability of the base screw to accommodate a threaded extension bolt.

U.S. Pat. No. 5,002,542 discloses a screw clamp wherein two horizontally disposed sections are adapted to receive the head of a pedicle screw for use in combination with a hook which holds a support rod at an adjustable distance.

U.S. Pat. No. 4,854,304 discloses the use of a screw with a top portion that is adaptable for use with a specially designed alignment rod to permit compression as well as distraction.

U.S. Pat. No. 4,887,596 discloses a pedicle screw for use in coupling an alignment rod to the spine wherein the screw includes a clamp permitting adjustment of the angle between the alignment rod and the screw.

U.S. Pat. No. 4,836,196 discloses a screw with an upper portion design for threadingly engaging a semi-spherical cup for use with a specially designed alignment rod. The alignment rod having spaced apart covertures for receipt of a spherical disc allowing a support rod to be placed at angular positions.

U.S. Pat. No. 5,800,435 sets forth a modular spinal plate assembly for use with polyaxial pedicle screw implant devices. The device includes compressible components that cooperatively lock the device along included rails.

U.S. Pat. No. 5,591,166 discloses an orthopedic bone bolt and bone plate construction including a bone plate member and a collection of fasteners. At least one of the fasteners allows for multi-angle mounting configurations. The fasteners also include threaded portions configured to engage a patient's bone tissue.

U.S. Pat. No. 5,569,247 discloses a multi-angle fastener usable for connecting patient bone to other surgical implant components. The '247 device includes fastening bolts having spherical, multi-piece heads that allow for adjustment during installation of the device.

U.S. Pat. No. 5,716,357 discloses a spinal treatment and long bone fixation apparatus. The apparatus includes link

members adapted to engage patient vertebrae. The link members may be attached in a chain-like fashion to connect bones in a non-linear arrangement. The apparatus also includes at least one multi-directional attachment member for joining the link members. This allows the apparatus to be used in forming a spinal implant fixation system.

Another type of spinal fixation system includes rigid screws that engage the posterior region of a patient's spine. The screws are adapted with rod-engaging free ends to engage a support rod that has been formed into a desired spine-curvature-correcting orientation. Clamping members are often used to lock the rod in place with respect to the screws. Instead of clamping members, other fixation systems, such as that disclosed in U.S. Pat. No. 5,129,900, employ connectors that join the support rods and anchoring screws. The connectors eliminate unwanted relative motion between the rod and the screws, thereby maintaining the patient's spine in a corrected orientation.

Unfortunately, although these so-called "rigid screw" fixation systems can alter the curvature of a patient's spine, they can also be difficult to install. In this type of system, the anchoring screws must be secured in a region that is strong/rigid enough to support the characteristically-large loads typically transferred from the support rods. As a result, the number of suitable anchoring locations is limited. Typically, these screws are anchored into the posterior region of a patient's spinal column or into pedicle bone. With rigid screw systems, installation requires bending a support rod into a path that will not only correct the shape a patient's spine but that will also engage each of the installed anchoring screws. Achieving a proper fit between all of the components while contending with the constraints encountered during surgery is often difficult. In severe cases, a suitable fit may not be achieved and the surgery will be unsuccessful.

Additionally, the nature of the installation process required for rigid screw fixation systems often subjects the system components to pre-loading that unduly stresses the interface between the patient's bone and the employed anchoring screws. With these designs, as a patient moves about during daily life, the system components may become separated from the supporting bone. Corrective surgery to reattach anchoring screws exposes an already-weakened region to additional trauma and presents the risk of additional damage.

Other spinal fixation systems employ adjustable components. For example, U.S. Pat. No. 5,549,608 includes anchoring screws that have pivoting free ends which attach to discrete rod-engaging couplers. As a result, the relative position of the anchoring screws and rods may be adjusted to achieve a proper fit, even after the screw has been anchored into a patient's spinal bone. This type of fixation system succeeds in easing the rod-and-screw-linking process. This adjustment capability allows the screws to accommodate several rod paths. Unfortunately, some adjustable fixation systems tolerate only limited amounts of relative adjustment between components, operating best when loaded in one of several preferred arrangements. As a result, many prior art adjustable fixation systems are suitable for only a few situations.

Additionally, many adjustable fixation systems are prone to post-surgery component loosening. As a patient moves about during day-to-day living, his spine is subjected to a seemingly-endless amount of dynamic loading. Almost all activity requires some form of back motion; over time, this cyclic movement tends to work the components of many adjustable fixation systems loose.

Some adjustable spinal fixation systems include locking mechanisms designed for long-term, post-surgery securement of the system components. Although capable of being locked in place, these systems are often difficult to secure, requiring an fexcess of tools during the installation process. The need for extra tools, such as those required to shave or crimp key portions of a fixation system, increasing surgical risk by adding complexity and increasing the number of required steps. Although locking-component fixation systems exist, many of them unduly increase the dangers of back implant surgery to an unacceptable level.

Hardware-intensive fasteners are disclosed in U.S. Pat. No. 5,549,608, in which anchoring screws are fitted with wrenching flats that allow an anchoring screw to be attached to a patient's spinal bone with the flats being trimmed away once the screw is in place. Clamping nuts are then used to secure the anchoring screws to included stabilizing rods.

Additionally, many spinal fixation systems do not permit component repairs. If, for example, a threaded portion of a connecting member becomes stripped or cross-threaded, the entire connector must be slid off of the associated stabilizing rod. Often, such removal produces an undesirable "domino-effect," requiring that several connectors be slid off to allow removal of the damaged connector. Such requirements add unnecessary difficulty to an already-complex procedure.

The bone screws shown and described in U.S. Pat. No. 5,628,740 and U.S. Pat. No. 6,050,997 have a bone screw with a spherical cavity in the proximal end. A toggle bolt with a spherical distal end is inserted into the cavity in the bone screw. A collet is forced into the spherical cavity superior to the spherical end of the toggle bolt. A support collar or attachment cap is placed over the toggle bolt and tightened down. This forces the retention collet to engage the spherical portion of the toggle bolt and the inside of the spherical cavity locking the toggle bolt in a selected angular disposition. This system requires extremely accurate machining of the threaded components to result in an optimum frictional fit. Further, because the collet is a ring, with a fixed inner diameter, there is only one correct size for the spherical components. Finally, any deformation of the ring will lessen the over-all frictional contact by creating wrinkles or ridges on the collet.

U.S. Pat. No. 5,876,459 to Powell teaches the use of a deformable collet to form a friction lock between components of an artificial hip. The collet is expanded outwardly to frictionally fix an artificial trochanter onto the neck of a ball joint.

U.S. Pat. No. 4,419,026 to Leto discloses a split ring camming internal locking device used with telescoping tubular members for transporting liquids. The ring is split for flexing to fit around the internal tube and for resiliently sealing against the external tube.

Thus, what is needed is a spinal fixation system that includes the advantages of known devices, while addressing the shortcomings they exhibit. The system should allow component adjustment during installation, thereby enabling satisfactory correction of a wide variety of spinal deformities. The system should also include a component locking mechanism that is simple and reliable. The system should include two-piece connectors that may be mounted along a support rod, in-between previously-secured connectors. The system should also include mounting hardware that secures with a minimum of tools and that allows modular replacement of components damaged during installation.

SUMMARY OF THE INVENTION

The present invention is a bone screw for use in a spinal fixation system for reshaping the spine of a patient. The bone

screw has threads on one end for anchoring in the spine. The other end has a spherical connector with a conical cavity therein. The cavity has the larger diameter base of the cone toward the threaded end of the screw and a narrower mouth. The mouth of the conical cavity accepts the spherical end of a toggle bolt such that the toggle bolt and the bone screw are connected by a ball joint. To prevent disassembly of the bone screw and toggle bolt, an associated split retention ring locking mechanism is inserted in the conical cavity between the spherical end of the toggle bolt and the mouth of the cavity. The resilient split retention ring can be compressed to reduce it's diameter for insertion through the mouth of the cavity and then expands to fill the conical cavity-superior to the spherical end of the toggle bolt.

Because of the flexibility and resilience of the split retention ring, the mating parts do not require fine tolerances and are less expensive to make. Further, the split retention ring provides infinite adjustment of the locking pressure as the toggle bolt is tightened into the assembly. The system is modular, employing a collection of anchoring assemblies that are linked, via various connectors, to strategically-arranged stabilizing rods. The stabilizing rods are shaped and aligned to impart a preferred curvature to a patient's spine.

The anchoring assemblies are multi-piece units characterized by linking members that are joined in a ball-and-socket-type arrangement with a corresponding bone-engaging member. During use, the bone-engaging member is secured to a spinal bone and the linking member is secured to one of the stabilizing rods via a corresponding connector. The bone-engaging member may include coarse, external threads or have a hook-shaped end. Each anchoring assembly also includes a support collar that provides a secure interface between the bone-engaging member and associated connector. Each anchoring assembly also includes a securing nut and a locking bolt that cooperate to prevent unwanted, post-installation motion within the anchoring assembly. The securing nut and locking bolt also prevent unwanted relative motion between the anchoring assembly and associated connector.

The connectors are rigid structures adapted to link an associated anchoring assembly with one of the stabilizing rods. In one embodiment, the connectors are two-piece constructions that allow the connector to engage a stabilizing rod in a sandwich-type arrangement, permitting connector installation and removal that does not disturb adjacent connectors.

The stabilizing rods are rigid members shaped to form a spine-curvature-correcting path. Attaching each anchoring assembly, via connectors, to a stabilizing rod forces a patient's back, into a surgeon-chosen shape. Stabilizing rods may be used singly, or in pairs, depending upon the type of correction required. The rods vary in size, but typically extend between at least two vertebrae.

Thus, it is an objective of the present invention to provide a bone screw assembly for a spinal fixation system that permits component adjustment during installation, thereby enabling satisfactory correction of a wide variety of spinal deformities.

It is an additional objective of the present invention to provide a bone screw assembly that includes a split ring locking mechanism that is simple and reliable.

It is a further objective of the present invention to provide a spinal fixation system that includes two-piece connectors that may be mounted along, and removed from, a support rod without requiring movement of adjacent connectors.

It is yet another objective of the present invention to provide a spinal fixation system that includes mounting hardware which requires a minimum number of tools.

It is also an objective of the present invention to provide a spinal fixation system that allows modular replacement of damaged components.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a pictorial view of the spinal fixation system of the present invention;

FIG. **2** is a perspective view of an anchoring assembly used in the present spinal fixation system;

FIG. **3** is a perspective view of an anchoring assembly used in the present spinal fixation system, having a support collar removed;

FIG. **3A** is a perspective view of a support collar used in the present spinal fixation system;

FIG. **4** is a pictorial view of a bone-engaging member from an anchoring assembly of the present invention;

FIG. **4A** is a pictorial view of a linking member from an anchoring assembly of the present invention;

FIG. **4B** is a pictorial view of a split retention ring of the present invention;

FIG. **5** is a pictorial view of an alternate embodiment of an anchoring assembly and connector of the present invention; and

FIG. **6** is a close-up view of an alternate embodiment of a split retention ring of the present invention.

FIG. **7** is a close-up view of the alternate anchoring assembly and connector shown in FIG. **5**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

It is to be understood that while a certain form of the invention is illustrated, it is not to be limited to the specific form or arrangement of parts herein described and shown. It will be apparent to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown in the drawings and described in the specification.

Now with reference to FIG. **1**, the spinal fixation system **10** of the present invention is shown. By way of overview, the Fixation System **10** includes a collection of bone-engaging anchoring assemblies **12** that are joined via connectors **14**,**14'** to stabilizing rods **16**, **16'**. The specifics of the spinal fixation system **10** will now be discussed in more detail.

With additional reference to FIG. **2**, one of the included anchoring assemblies **12** is shown in an assembled state. FIGS. **3** and **3A** show the anchoring assembly with an associated support collar **18** removed. In addition to the support collar **18**, each anchoring assembly **12** also includes a pedicle screw **20**, a toggle bolt **22**, and a split retention ring **24**. As shown in FIG. **4**, each pedicle screw **20** also includes a ball end **28** spaced apart from the threaded end **26** by a

neck portion 30. The exterior 32 of the pedicle screw ball end 28 is preferably contoured for easy grasping. The interior of the pedicle screw ball end 28 forms a retention cavity 34, discussed below. The entrance 36 to the retention cavity 34 is characterized by a securing lip 38 that extends radially into the retention cavity 34.

Each toggle bolt 22, as shown in FIG. 4A, includes a ball end 40 and an opposite threaded end 42. As seen in FIG. 3, the ball end 40 of the toggle bolt 22 is shaped and sized to fit inside the pedicle screw retention cavity 34. Preferably, the interior of the retention cavity is substantially conical but slightly larger dimensions than the spherical contours of the toggle bolt ball end 40.

With reference to FIG. 4B, the split retention ring 24 includes a gap 44 separating the opposite ends of the split retention ring main body 46. As seen in FIG. 3, the split retention ring 24 is used as a bracing means to secure the ball end 40 of the toggle bolt 22 within the pedicle screw retention cavity 34. More specifically, after the toggle bolt ball end 40 is placed within the pedicle screw retention cavity 34, the split retention ring 24 is pushed through the entrance 36 of the retention cavity 34 by reducing the gap 44 facilitating travel past the engagement lip 38, thereby bringing the split retention ring main body 46 to rest against the engagement lip by spring action resilience of the split retention ring 24.

With this arrangement, the split retention ring 24 allows pivotal movement of the toggle bolt 22 within the retention cavity 34, while preventing removal of the toggle bolt therefrom. Once the split retention ring 24 and toggle bolt 22 are in place, the threaded end 42 of the toggle bolt is inserted through a passthrough aperture 48 of the support collar 18. This is shown in FIG. 2.

Once the toggle bolt 22 has been passed through the support collar passthrough aperture 48, the support collar 18 comes to rest against the pedicle screw ball end 28. Although several shapes are possible, the interior of the support collar 18 preferably has a spherical contour that matches the exterior 32 of the pedicle screw ball end 28. This arrangement limits the relative motion possible between the support collar 18 and the toggle bolt 22, while allowing the toggle bolt ball end 40 to rotate freely within the pedicle screw retention cavity 34. Although an assembly process has been described above, the anchoring assemblies 12 are typically delivered to the end-user surgeon as a finished unit.

With additional reference to FIG. 3, the threaded interior bore 122 of the toggle bolt threaded end 42 has a hexagonal cross section. This allows the insertion of an allen wrench, not shown, into the interior bore 122 to prevent relative motion between the spherical ball end 40 of the toggle bolts 22 and the conical retention cavity 34 of the pedicle screw 20. The inserted allen wrench thereby prevents unwanted spinning of the toggle bolt 22 within the retention cavity 34 while the securing nut 116 is tightened onto the exterior threads 120.

Tightening the securing nut 116 forces the toggle bolt threaded end 42 to travel longitudinally through the passthrough aperture 84 and also causes the toggle bolt ball end 40 to be forced against the split retention ring 24 reducing the gap 44. Further tightening of the securing nut 116 forms a substantially rigid fit between the toggle bolt 22 and the pedicle screw 20. With the securing nut 116 tightened appropriately, the toggle bolt threaded end 42 is locked in place with regard to the right-facing straight connector attachment flange 82, and the toggle bolt ball end 40 is locked in place within the pedicle screw retention cavity 34. In this state, the split retention ring is sandwiched between the exterior of the toggle bolt ball end 40 and the conical interior of the retention cavity 34. Since the split retention ring 24 is locked within the retention cavity 34 by the retention cavity engagement lip 38, relative motion between the toggle bolt ball end and the pedicle screw 20 is prevented once the toggle bolt threaded end 42 is locked in place by the tightened securing nut 116. This results in a rigid link between the right-facing straight connector and the anchoring assembly 12.

Although the above description refers to joining an anchoring assembly 12 specifically to a right-facing straight connector 52, each of the one-piece connectors 14 and two-piece connectors 14' may be attached to an anchoring assembly in a similar manner. That is, right-facing offset connectors are attached by inserting a toggle bolt threaded end through the associated passthrough aperture; left-facing offset connectors are joined with an anchoring assembly by inserting a toggle bolt threaded end through an associated passthrough aperture; and left-facing straight connectors are attached to anchoring assemblies by inserting a toggle bolt threaded end through an associated pass-through aperture. In each case, the exterior threads 120 of the inserted toggle bolt threaded end 42 are held in place by a tightened securing nut 116, as described previously.

To prevent unwanted loosening of a connector 14, 14' and anchoring assembly 12 union, a locking bolt 118 is inserted into the threaded interior bore 122 of the toggle bolt corresponding to each anchoring assembly that has been secured in place. As mentioned above, each locking bolt 118 has a left-handed thread pattern, thereby matching the left-handed thread pattern of each toggle bolt threaded interior bore 122. The locking bolt 118 is screwed into an associated toggle bolt threaded interior bore 122 until the locking bolt head plate comes to rest against the securing nut 116 that holds the corresponding anchoring assembly 12 in place with respect to the associated connector 14, 14'. Incorporating this locking bolt 118 ensures that anchoring assemblies 12 and connectors 14, 14' stay locked in place, thereby preventing unwanted relative motion within the spinal fixation system 10.

Now with reference to FIG. 5, an alternate embodiment of an anchoring assembly 12' is shown secured to a right-facing straight; connector 52. In this embodiment, a alternate split retention ring 24' is used to secure the toggle bolt ball end 40 within a securing cavity 34' disposed within the ball end 28 of an associated pedicle screw 20'. The securing cavity 34' has a conical wall 45 tapering from a wider base toward a narrower mouth. Relative position between the pedicle screw 20 and the connector 52 is maintained by an associated support collar 18. The support collar 18 is disposed between the pedicle screw ball end 28' and the attachment flange 82 of the connector 52.

With reference to FIG. 6, a close-up view of an alternate embodiment of the split retention ring 24' is shown. The exterior surface of the ring 24' is characterized by conical shaped wall 46' and a gap 44'. With additional reference to FIG. 7, the conical wall of the split retention ring 24' is complimentary to the conical wall of retention cavity 34. Additionally, interior surface of the conical split retention ring 24' has a smaller diameter circular shoulder 47 shaped and sized to engage the exterior surface of an associated toggle bolt ball end 40.

The spinal fixation system 10 is preferably formed from rigid, biocompatible materials. One such preferred material is titanium; however, other materials may be used as well.

Although the invention has been described in terms of a specific embodiment, it will be readily apparent to those skilled in this art that various modifications, rearrangements and substitutions can be made without departing from the spirit of the invention. The scope of the invention is defined by the claims appended hereto.

What is claimed is:

1. In an anchoring assembly for insertion in skeletal bone, said anchoring assembly having a linking member having a threaded first end and a substantially-spherical second end;

a bone-engaging member having a first end adapted to engage said bone and a second end comprising a retention cavity constructed and arranged to engage said linking member second end, said retention cavity having a substantially-spherical exterior surface and a circular open mouth;

the improvement comprising a bracing device in said retention cavity for selectively maintaining said linking member second end in a chosen orientation within said retention cavity, said bracing device in the form of a split retention ring having a diameter greater than the diameter of said circular open mouth and adapted to frictionally engage said linking member second end; and

a support collar adapted for placement against said bone-engaging member second end, said collar having a contoured surface sized and shaped to adjustably engage said exterior surface of said bone-engaging member second end;

said support collar includes a securing nut mounted on said threaded first end of said linking member;

said split retention ring comprising a main body having a substantially-circular cross section and a gap, the diameter of said circular cross section being smaller than the diameter of said linking member spherical second end, thereby preventing removal of said linking member second end from within said retention cavity, said retention cavity has a conical inside wall, said wall narrowing toward said circular mouth, whereby tightening of said securing nut draws said linking member second end against said split retention ring forcing said split retention ring along said narrowing conical inside wall reducing said gap and applying progressive pressure on said linking member.

2. In an anchoring assembly of claim 1, wherein said first end of said bone-engaging member has screw threads to engage said bone.

* * * * *

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United States Patent [19]

Ganem

[11] Patent Number: 6,022,350

[45] Date of Patent: Feb. 8, 2000

[54] **BONE FIXING DEVICE, IN PARTICULAR FOR FIXING TO THE SACRUM DURING OSTEOSYNTHESIS OF THE BACKBONE**

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[73] Assignee: **Stryker France S.A.**, France

[21] Appl. No.: **08/854,412**

[22] Filed: **May 12, 1997**

[30] **Foreign Application Priority Data**

May 13, 1996 [FR] France 96 05898

[51] **Int. Cl.**[7] **A61B 17/70**

[52] **U.S. Cl.** **606/61**; 606/69; 606/73

[58] **Field of Search** 606/69, 70, 71, 606/61, 60, 72, 73

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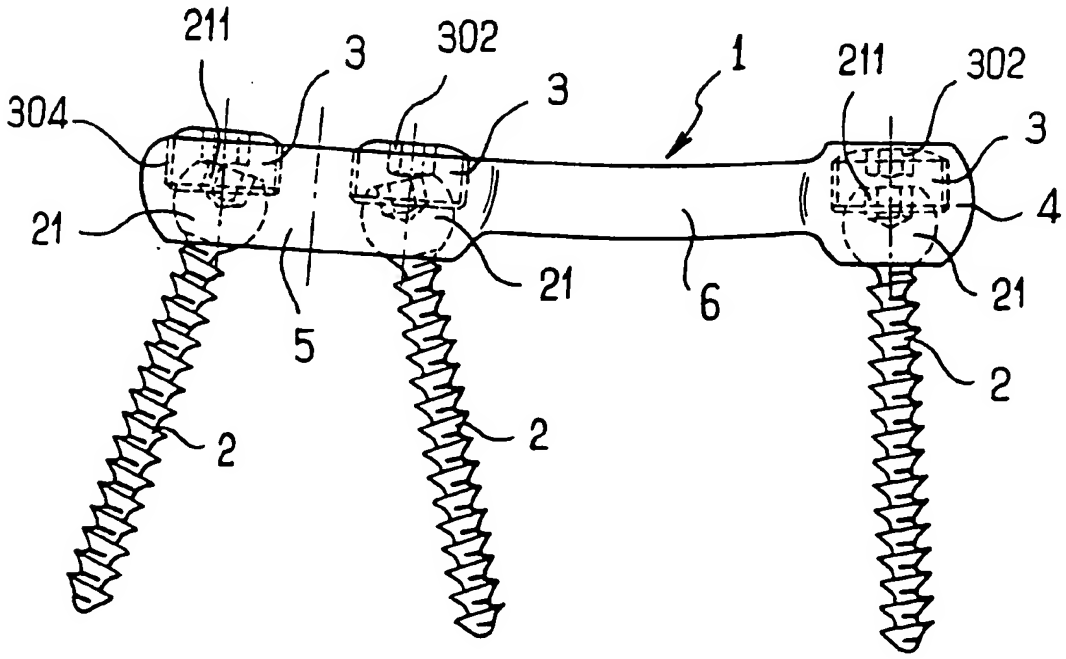
Primary Examiner—Michael Buiz
Assistant Examiner—David O. Reip
Attorney, Agent, or Firm—Blakely Sokoloff Taylor & Zafman

[57] **ABSTRACT**

A bone fixing device, in particular for fixing to the sacrum for osteosynthesis of the backbone, comprises elongate link means receiving at least one bone-fastening screw, which passes through an orifice formed in the link means. In the bottom of the link means there is included a bearing surface of essentially circular cross-section. The head of the screw includes an essentially spherical surface for bearing against said bearing surface. The link means include a first thread in the vicinity of said orifice. The device further includes a plug having a second thread suitable for co-operating with the first thread, the plug being suitable for coming into clamping contact against said screw head to hold it in a desired angular position. According to the invention, the link means are constituted by a single-piece plate-shaped element having the orifice and the first thread formed therein, and said bearing surface is essentially spherical.

20 Claims, 6 Drawing Sheets



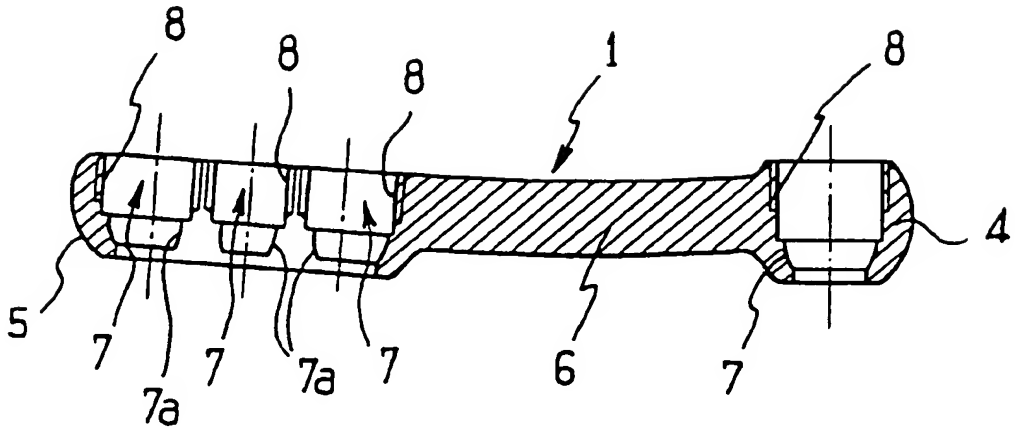


FIG_1

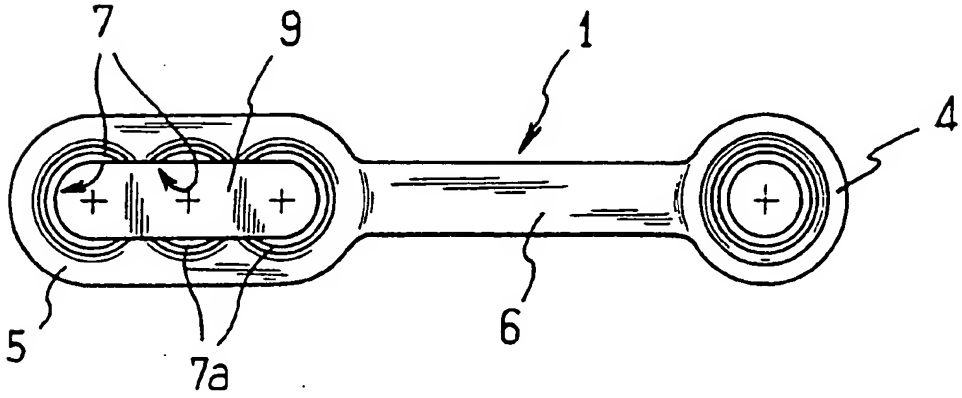


FIG_2

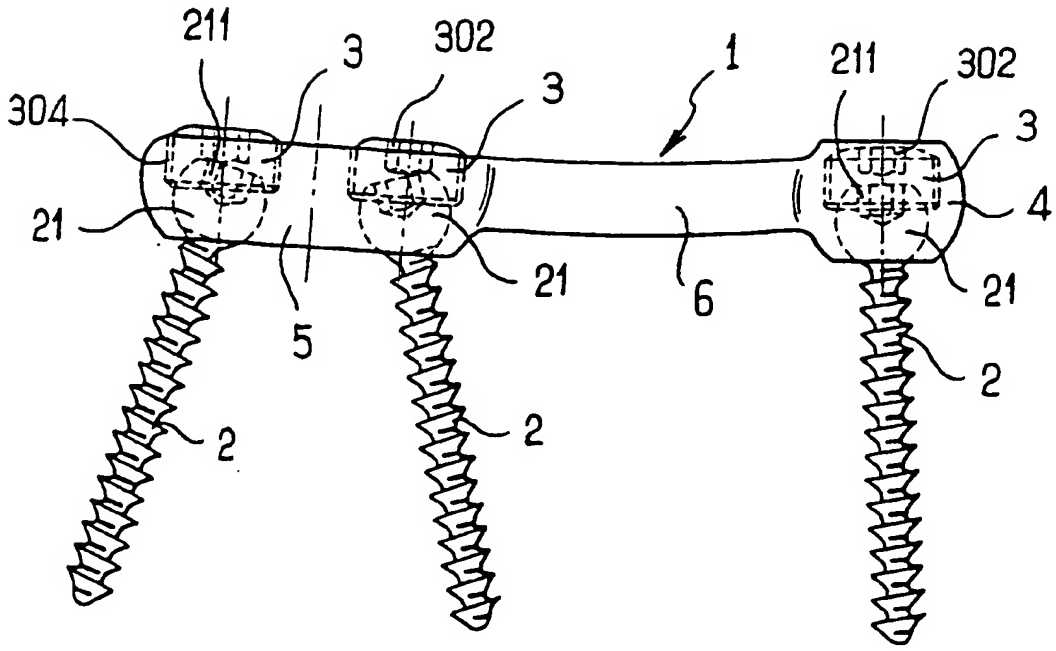


FIG_3

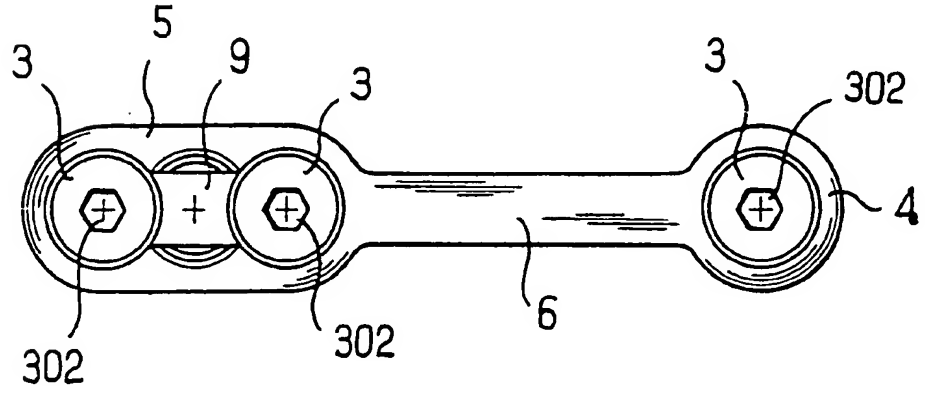


FIG_4

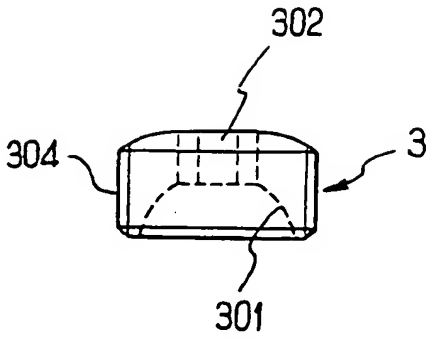


FIG_5

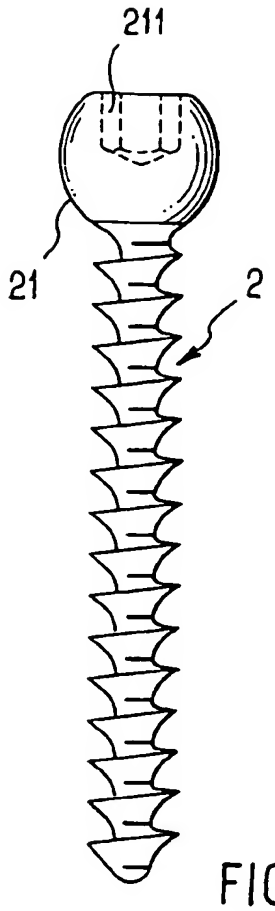


FIG_6

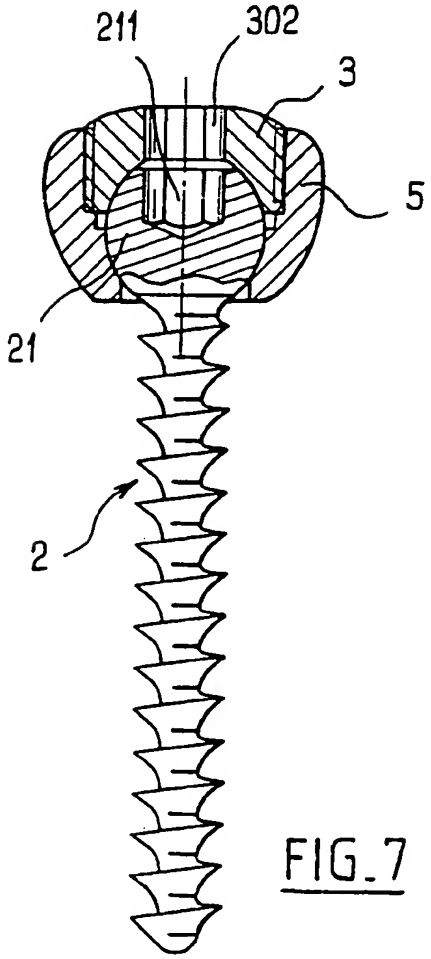


FIG_7

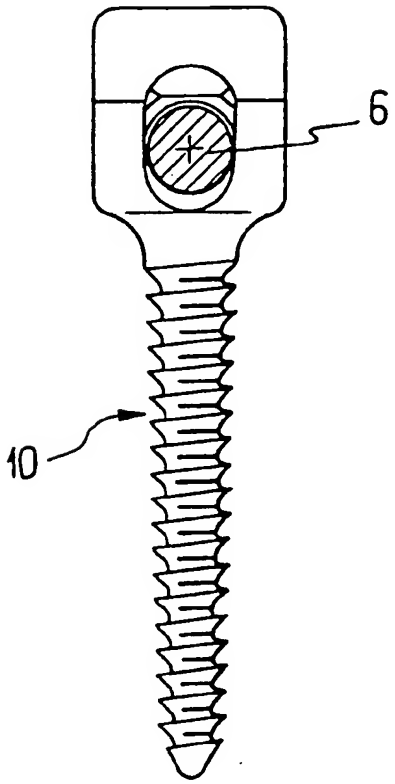


FIG_8

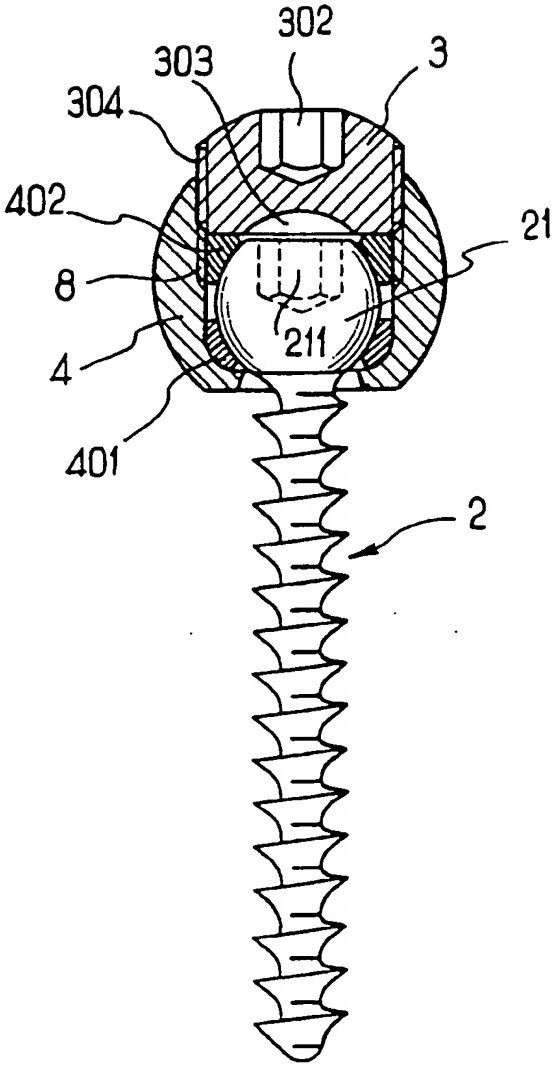


FIG_9

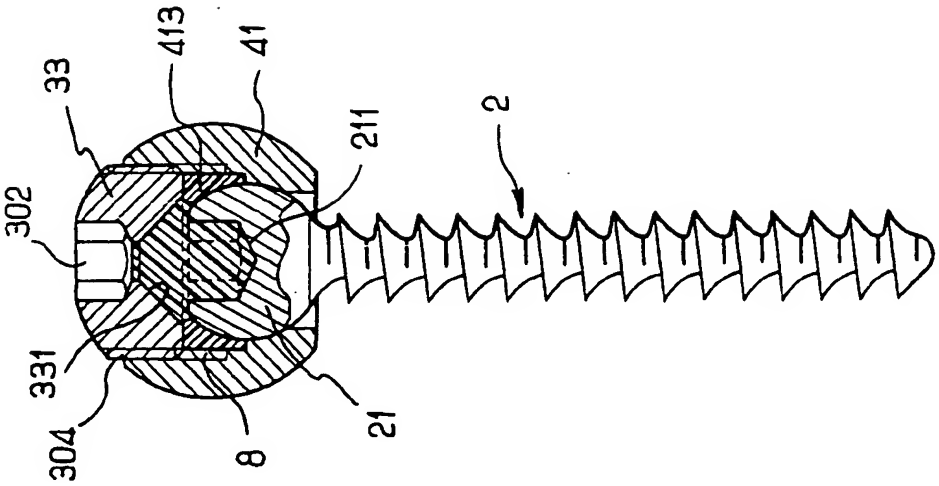


FIG_12

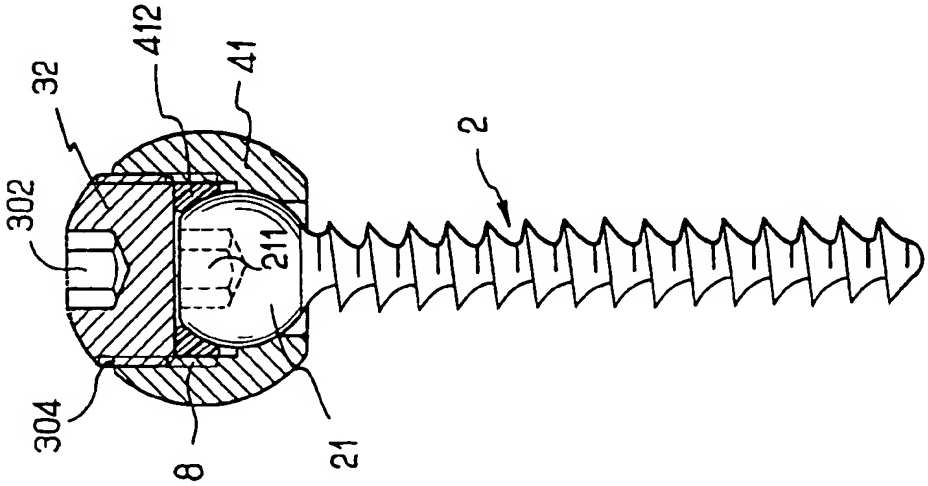


FIG_11

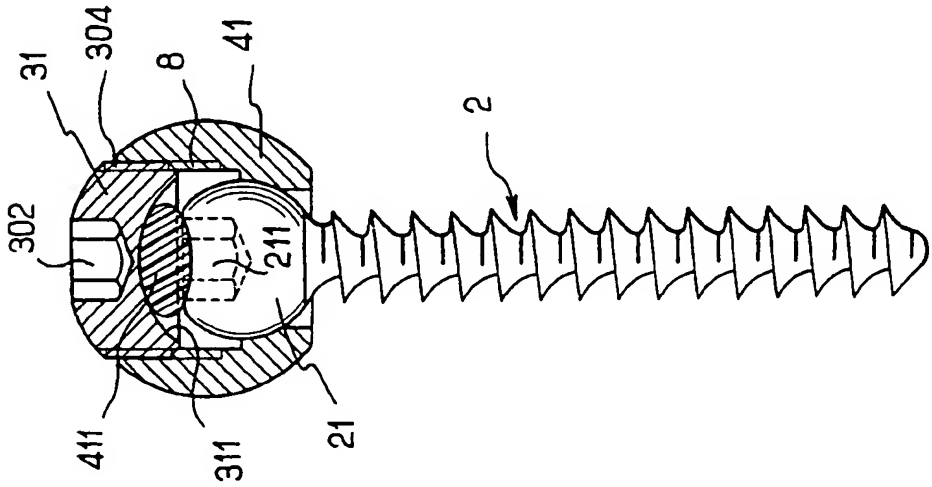


FIG_10

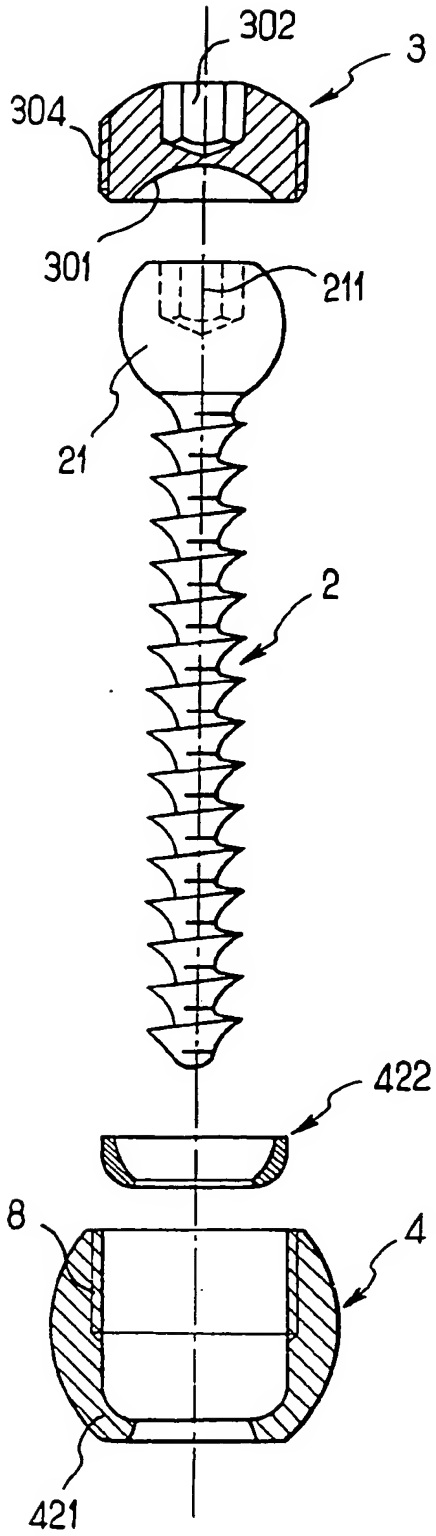


FIG.13

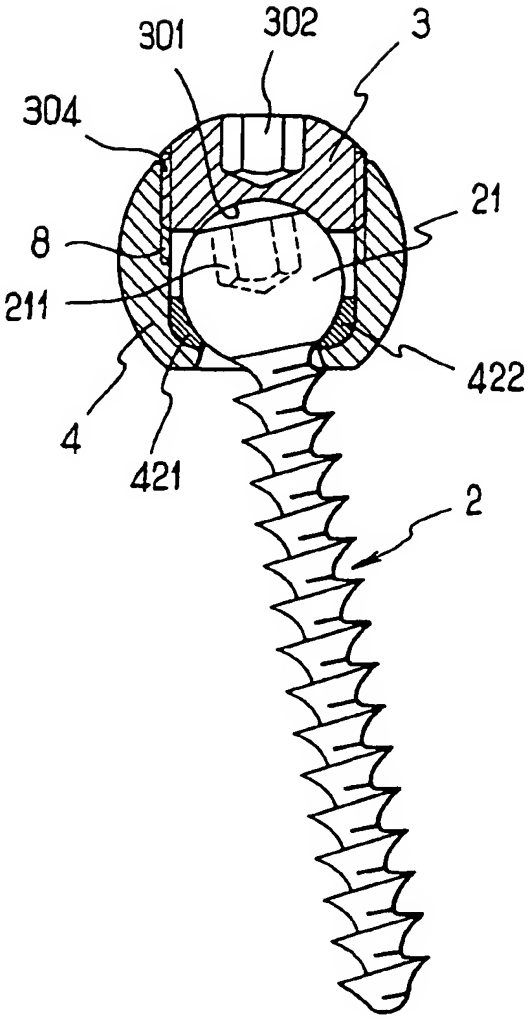


FIG.14

BONE FIXING DEVICE, IN PARTICULAR FOR FIXING TO THE SACRUM DURING OSTEOSYNTHESIS OF THE BACKBONE

The present invention relates in general to a fixing device, in particular for fixing to the sacrum and usable during osteosynthesis of the backbone.

BACKGROUND OF THE INVENTION

It is commonplace to perform osteosynthesis of the backbone by using fixing devices that are fastened to the sacrum. This makes it possible to perform reduction movements between the various fixed stages, which movements can be contractions, distractions, or indeed reversals of vertebrae that have slipped forwards relative to the backbone, where the latter condition is known as "spondylolisthesis".

Distraction is often performed for reduction of spondylolisthesis. Partial reduction is thus obtained by putting the fibers of the patient's ligament and disk apparatus back under tension. Reduction is completed by using equipment in accordance with the operating technique associated therewith. Except under exceptional circumstances, the operation is performed bilaterally. Throughout the description below, only one side of the treatment is described.

Most blocks or plates known in the prior art for fixing to the sacrum suffer from certain drawbacks. One of these drawbacks lies in that the orientation of the bone-fastening screws is fixed, which means that the device clearly lacks flexibility in use, given variations from one patient to another concerning the configuration of the sacrum and the neighborhood thereof.

Another drawback of known plates or blocks for fixing to the sacrum lies in the risk of the fastening screws becoming unscrewed, particularly under the effect of relative micro-movements that occur between the equipment and the sacrum. This can result in failure of the fixing to the sacrum.

Also, backbone osteosynthesis can be performed by using equipment serving to fix various functional units of the spinal column, often in a very rigid manner. This gives rise to a sudden change in the distribution of forces, and thus to resulting stress and deformation states for the disks underlying and overlying the fixing. At some stage in the long term, this modification gives rise to degeneration of the disks. This condition is known as the "hinge syndrome".

Document EP-A-0 625 337 discloses a bone fixing device, in particular for fixing the sacrum for osteosynthesis of the backbone, the device comprising elongate link means receiving at least one bone-fastening screw, which screw passes through an orifice formed in the link means, in which the link means include in the bottom region thereof a bearing surface of essentially circular cross-section, in which the head of the screw has a surface that is essentially spherical for bearing against said bearing surface, and in which the link means include a first thread in the orifice, the device also including a plug having a second thread suitable for co-operating with the first thread and for coming into clamping contact with said screw head to hold it in a desired angular position. That device enables the inclination of the screws relative to an elongate link element to be varied, and it also enables the spacing between the screws to be varied.

Nevertheless, that known device is disadvantageous in that the elongate link means are constituted by a plurality of components, specifically an elongate member of cup-shape and a plurality of fixing blocks distributed along the elongate member, each receiving the head of a screw, and at the bottom, a zone corresponding to the elongate member.

This means that it is extremely fiddly for the surgeon to handle the device and put it into place, and in particular it is necessary to slide a series of fixing blocks along the elongate member, and to hold them in position thereon.

OBJECTS AND SUMMARY OF THE INVENTION

A first object of the present invention is to mitigate that drawback.

To this end, the invention provides a bone fixing device of the type defined above, wherein the link means are constituted by a single-piece plate-shaped element having the orifice and the first thread formed therein, and wherein said bearing surface is essentially spherical.

Preferred, but non-limiting aspects of the device of the invention are the following:

the first thread is a tapping formed internally in the orifice at a distance from said bottom, and the plug has an outside thread;

the screw head also has a generally spherical top, and the plug has a complementary internal spherical cavity;

said plate includes a series of orifices in alignment that are interconnected by a slot enabling a bone-fastening screw to be moved from one orifice to another before tightening;

said screw head and said plug have identical tightening sockets;

said plate is designed to be fixed to a first bone and forms an integral portion of an element that also includes an eyelet for another bone-fastening screw for fastening to a second bone, together with a rod interconnecting said plate and said eyelet;

the device further includes a bone-fastening device for fastening to another bone, to which said rod is fixed;

the device includes at least two bone-fastening screws passing through respective orifices formed in said plate, and the two screws are suitable for taking up two different angular positions;

the device further includes means for attenuating the stiffness of the assembly between at least one of the bone-fastening screws and said element;

said means for attenuating stiffness comprise at least one piece of flexible material interposed and compressed between said screw head and the associated plug;

the device is associated with a plurality of pieces of flexible material having different flexibilities, thereby enabling different degrees of stiffness attenuation to be provided without requiring action to be taken on the torque with which the plug is tightened;

said piece is an O-ring;

said piece is a pellet;

said stiffness attenuation means comprise a thixotropic fluid interposed between and compressed between the plug and said screw head;

said spherical bearing surface of said orifice is formed by deforming an O-ring placed in a bottom region of said orifice;

said spherical bearing surface of said orifice is constituted by a surface of a rigid ring fitted in a bottom region of said orifice;

said rigid ring is made of a material selected from the group comprising: ceramic-coated titanium alloys, titanium alloys treated by ion bombardment, and solid ceramics;

the stiffness attenuation means further include a surface coating suitable for reducing friction between said essen-

tially spherical bearing surface and said complementary surface of the screw head; and

said surface coating is made by nitrogen ion bombardment.

BRIEF DESCRIPTION OF THE DRAWINGS

Other aspects, objects, and advantages of the present invention appear more clearly on reading the following detailed description of preferred embodiments thereof given by way of example and made with reference to the accompanying drawings, in which:

FIG. 1 is a mid longitudinal section view through a fixing element of the invention;

FIG. 2 is a front view of the FIG. 1 element;

FIG. 3 is a side view of the element together with three bone-fastening screws and the associated plugs;

FIG. 4 is a front view of the element provided with screws and plugs;

FIG. 5 is a side view in elevation of a plug for co-operating with the screw of FIG. 6 and the element of FIGS. 1 and 2;

FIG. 6 is a side view in elevation of a bone-fastening screw for co-operating with the element of FIGS. 1 and 2;

FIG. 7 is a cross-section view of the fixing element, a bone-fastening screw, and the associated plug, after assembly;

FIG. 8 is a view partially in elevation and partially in section through an auxiliary bone-fastening screw designed to co-operate with another portion of the fixing element of FIGS. 1 and 2;

FIGS. 9 to 12 are cross-section views analogous to FIG. 4, through four variant embodiments of the invention;

FIG. 13 is a cross-section view through the various components of a fifth variant embodiment of the invention; and

FIG. 14 is a cross-section view through the fifth variant in the assembled state.

MORE DETAILED DESCRIPTION

As a preliminary point, it should be observed that elements or portions that are identical or similar from one figure to another are designated, wherever possible, by the same reference symbols, and are not described again on each occasion.

With reference now to FIGS. 1 and 2, there can be seen a sacrum-fixing element given overall reference 1 and made up of three portions: an upper eyelet 4, a sacrum plate 5, and a rod 6, e.g. a cylindrical rod, interconnection the eyelet and the plate. In profile, the overall shape of the element 1 is curved to comply with lordosis, as can be seen in FIG. 1.

A series of holes 7 is formed through the plate 5 in alignment with the long direction of the element 1 and for receiving bone-fastening screws 2.

Preferably, a range of models for the element 1 is offered to the surgeon, different models having, in particular, different lengths of rod 6, and within the plate 5, different numbers of holes for bone-fastening screws.

As shown in FIG. 3, in a three-hole version, the plate 5 may receive two bone-fastening screws 2, while in a five-hole version (not shown), it may receive three bone-fastening screws 2.

The holes 7 are in communication with one another via an oblong section through slot 9 as can be seen in FIG. 2. This slot makes it easy to pass a screw 2 from one position to another while performing reduction. In the region of its bottom, each of these holes includes a spherical cup 7*a* for co-operating with a complementary bottom portion of the head 21 of the screw 2, said head 21 being generally spherical in shape and having a tightening socket 211, e.g. of the hexagonal type.

This shape for each hole 7 and for the associated screw head 21 allows each screw to move within a solid angle where the half-angle at the apex is, for example, of the order of 30°.

In addition, since each screw is stabilized in its housing while it is being installed, two screws that are distant from each other are suitable for maintaining bone distraction without requiring the use of a distractor instrument.

As shown in particular in FIGS. 1 and 7, each hole 7 possesses internally, at a distance from the cup 7*a*, a thread in the form of a tapping 8 which enables it to receive a plug 3, shown in detail in FIG. 5. The outside face of the plug includes a tightening socket 302 which is preferably identical to that in the screw head 21 so that the same tightening tool can be used, and a spherical cup-shaped housing 301 co-operating with the similarly spherical top of the screw head 21. The periphery of the plug is threaded at 304 in order to co-operate with the tapping 8 in the hole 7. The purpose of the plug 3, after being screwed into place and tightened, is to lock the screw 2 in an angular position as determined by the surgeon.

The plate 5, the screw 2, and the plug 3, once assembled together, are shown in FIG. 7. The threaded plug 3 performs a non-return function preventing any accidental unscrewing of the associated bone-fastening screw 2, particularly under the conditions explained in the preamble of the present application.

Also, by means of the device of the present invention, spondylolisthesis can be reduced by implanting in the pedicle of the vertebra concerned either an intermediate screw fixed on the intermediate link rod 6, or a screw placed in the eyelet 4.

In the first case, the intermediate rod 6 can thus be used to reverse the vertebra. To this end, and as shown in FIG. 8, it can be associated with a top-loading screw, given overall reference 10 and known per se, and which is previously implanted in the vertebra in question.

It is also possible to secure the vertebra that is to be moved to the intermediate rod 6 by means of a different type of device that is not shown, but that is likewise known per se, in which the screw is offset relative to the axis of the rod 6 but is connected thereto by a holding system.

In the second case, it is the top eyelet 4 of the element 1 which is used to receive the bone-fastening screw 2 engaged in the vertebra that is to be treated, said screw 2 being preferably of the same type as described above. To this end, a hole 7 identical to that described with reference to the plate 5, is formed through said eyelet, so as to allow the screw 2 to be moved angularly and so as to provide a non-return function by means of a plug 3, thus preventing the screw becoming loose.

In order to avoid giving rise to the hinge syndrome as described in the preamble, it is possible to avoid locking firmly the screw 2 that is inserted through the top eyelet 4. Under such circumstances, the screw 2 retains a certain amount of mobility relative to the eyelet 4.

In this way, the position of the vertebra in which the screw 2 inserted through the eyelet 4 is engaged is indeed fixed, but

the underlying intervertebral disk continues to function, to some extent. A rigidity gradient is thus established in the fixing which has the effect of attenuating the sudden change of stress state at the overlying disk.

This relative mobility between the screw **2** and the eyelet **4** can be provided in various ways.

A first technique, not shown, consists in using the same principle as that shown in FIG. **7**, i.e. using a threaded plug **3** and providing a shoulder in the hole **7** in the eyelet that prevents the plug **3** from reaching a position in which it locks the angular position of the screw **2**.

In a variant, also not shown, such a shoulder may be formed on the threaded plug **3**.

Also, or alternatively, it is possible to reduce friction between the plug **3** and the head **21** of the screw **2** to a negligible quantity by applying a thin layer of a low coefficient of friction coating, e.g. of ceramic type or of diamond like carbon, on one or more of the various surfaces in contact, i.e. the head of the screw **21**, the cup **7***a* of the hole **7** in the eyelet **4**, and the cup **301** in the threaded plug **3**.

For example, such a coating may be applied solely to the head **21** of the screw **2**.

With reference now to FIGS. **9** to **14**, several variant embodiments are described that serve to attenuate the stiffness of the assembly between the screw **2** and the eyelet in which it is engaged, likewise for the purpose of avoiding the hinge syndrome.

Thus, FIG. **9** shows a technique in which all contact is avoided between the rigid parts that need to move relative to one another by using a bottom, first O-ring **401** and a top, second O-ring **402**. These two rings are preferably made of a damping material such as silicone, and they are shown in FIG. **9** in the deformed state after the plug has been tightened.

Thus, when the rings **401** and **402** are compressed and deformed during tightening, they provide a connection of attenuated stiffness between the screw **2** and the eyelet **4**.

Advantageously, rings having different hardness characteristics but all having the same dimensions, are made available to the surgeon, thereby enabling the surgeon to vary the stiffness of the assembly without having to adapt the extent to which the threaded plug **3** is tightened, since that can be very difficult to implement in reliable manner.

Also, in order to minimize friction between the rings **401** & **402** and the head **21** of the screw, it may be advantageous to apply surface treatment to the screw by nitrogen ion bombardment, thereby improving the tribological characteristic of the head of the screw.

Still with reference to FIG. **9**, it can be seen that in this case the plug **3** continues to have a spherical cup **303** that is intended solely to enable the angle of the screw **2** to be varied but without applying locking thrust against the head **21** of said screw.

FIG. **10** shows a variant in which the plug **31** differs from that of FIG. **5** in that its cup, referenced **311** is no longer complementary to the spherical head **21** of the screw **2**, but is more flared, so that a pellet **411** of damping material can be interposed between the cup **311** and said head **21**, and can be compressed and deformed when tightening the plug.

This also provides attenuation of the overall stiffness of the assembly.

FIG. **11** shows a variant in which the threaded plug **32** has a plane working surface and in which direct contact between the plug **32** and the head of the screw **21** is avoided by using an O-ring **412** made of a damping material, which is compressed and deformed when the plug is tightened.

FIG. **12** shows a variant in which the plug, given reference **33**, has a conical recess **331** in its working face, and in which contact between the plug **33** and the screw head **21** is avoided by injecting a thixotropic fluid **412** while the appliance is being installed, thereby likewise performing the damping function.

In addition, in the three variant embodiments of FIGS. **10**, **11**, and **12**, contact friction between the spherical head **21** and the cup **7***a* of the hole **7** formed in the eyelet **4** can also be reduced by using a coating of the kind mentioned above. In this respect, the coating used in the variant of FIG. **12** should be selected so that contact between the base of the spherical head **21** and the cup **7***a* seals the thixotropic fluid even when compressed by tightening the plug.

FIGS. **13** and **14** show another variant embodiment in which the eyelet is modified. More precisely, the eyelet **4** has a generally cylindrical cup **421** in which the portion remote from the bottom is tapped at **8** to receive the threaded plug **3**, identical to that of FIG. **5**.

A ring **422** is interposed between the cup **421** and the screw head **21**. It may either be a rigid ring, e.g. made of a ceramic-coated titanium alloy, or of titanium alloy treated by ion bombardment, or indeed of solid ceramic, or else it may be an O-ring identical to the ring **401** used in the variant embodiment of FIG. **9**, likewise made of a damping material, e.g. silicone.

When the ring **422** is rigid, it may be advantageous for the radius of curvature of its internal spherical bearing surface to have a value that is slightly smaller than the radius of the screw head **21**, so as to ensure that said screw head is stressed on tightening. In which case the version of FIGS. **13** and **14** can advantageously also be used when it is desired to lock the screw fully.

In another variant, the ring **422** can be split, there again with the head **21** being put under stress and with the option of locking.

Naturally, the parts such as the element **1**, the screws **2**, and the plugs **3** are all made of biocompatible materials having appropriate mechanical properties, e.g. a titanium alloy.

Various additional remarks are given below to finish off.

Firstly, the shape and the dimensions of the element **1** are selected so as to enable it to withstand twisting stresses, by means of the plane bearing surface generated between the base of the plate-shaped portion **5** and the adjacent bone.

This shape also makes it possible to limit movement in longitudinal translation on the intermediate screws.

Thereafter, the above-described means for attenuating stiffness provide such attenuation both in the sagittal plane and in the transverse plane.

Finally, the invention makes it possible to offer an osteosynthesis system that is highly modular: thus, for example, different versions of the ring **422** can be offered to the practitioner for adjusting the anterior contact zone (adjacent to the vertebra), whereas one of the above-described damping means can be offered with various different degrees of stiffness so as to adapt damping in the posterior portion (adjacent to the plug). In practice, this makes it possible to cover the entire range between flexible links and rigid links.

In this respect, it will be observed that the above-described stiffness-attenuating means can be used both with the screw in the eyelet **4** and with the screws in the plate **5**.

Naturally, the present invention is not limited in any way to the various embodiments described and shown, and the person skilled in the art will be able to make variations or modifications within the spirit of the invention.

I claim:

1. A bone fixing device for fixing the sacrum to an adjacent vertebra during osteosynthesis of the backbone, the device comprising:

a plurality of bone fastening screws, each screw having a head wherein at least one of the plurality of bone fastening screws is a top-loading screw;

an elongated member having a first portion and second portion coupled between a cylindrical rod having a cylindrical circumference, each portion and the cylindrical rod being in general alignment relative to one another, the elongated member further having a means for receiving at least two bone-fastening screws at an angle in the first portion and for receiving at least one bone fastening screw at an angle in the second portion, the heads of each bone fastening screw being in general alignment relative to one another;

wherein the top-loading screw is fixed about the cylindrical circumference of the cylindrical rod; and

a means for securing each bone fastening screw to the elongated member at an angle.

2. The device of claim 1,

the head of each screw having a bottom portion, the bottom portion having a spherical profile,

each means for receiving comprising an orifice through which a bone fastening screw may pass, the orifice further defined by a bottom region and a top region, the bottom region having a spherical profile complementary to the spherical profile of the screw head so as to act as a bearing surface, the top region having first threads,

the means for securing comprising a plug, the plug having second threads adapted to cooperate with the first threads of the top region of the orifice to clamp a bone fastening screw to the elongated member at an angle.

3. The device of claim 2, the head of each screw having a top portion, the top portion having a spherical profile that extends from the bottom portion of the head, the plug further having a concave spherical profile complementary to the spherical profile of the top portion of the screw head.

4. The device of claim 2 wherein each orifice of the first portion is connected by a single longitudinal slot that permits the movement of one bone fastening screw from one bearing surface to another bearing surface without extracting the bone fastening screw from the orifice.

5. A bone fixing device for use in osteosynthesis of the backbone, the device comprising:

an integral link member having a longitudinal direction, a top region having a plurality of first threads, a bottom region, a plurality of spherical bearing surfaces in the bottom region, each spherical bearing surface being adjacent to at least one other spherical bearing surface in the longitudinal direction and associated with one first thread in the top region, the integral link member further having an elongated through orifice coupling each spherical bearing surface;

at least one bone fastening screw adapted to be received in the elongated orifice whereby the bone fastening screw may be moved from one bearing surface to another bearing surface without extracting the screw from the orifice, each screw having a head with an essentially spherical surface adapted to bear against a spherical bearing surface of the integral link member; and

at least one plug having a second thread adapted to cooperate with one of the first threads and further adapted to come into clamping contact with the head of at least one bone fastening screw to hold the screw against one of the bearing surfaces in a desired angular position.

6. The device of claim 5 further comprising at least one transition region, wherein each of the bearing surfaces and its associated first threads are mutually truncated at one of the transition regions therebetween.

7. The device of claim 5, the elongated through orifice having an end and a major axis having a direction, the integral link member further having a linking portion, the linking portion adapted to extend from one end of the elongated through orifice in a direction corresponding to the major axis of the elongated through orifice.

8. The device of claim 5, the head of each screw further having a top portion of an essentially spherical shape, the plug further having a bottom surface, the bottom surface having a spherical cavity that is complementary in shape to the spherical shape of the top portion of each screw head.

9. The device of claim 5 wherein the elongated through orifice has a length adapted to simultaneously receive at least two bone fastening screws and at least two corresponding plugs.

10. A bone fixing device for use in osteosynthesis of the backbone, the device comprising:

a link member having a through orifice, the through orifice having a top region having a first thread and a bottom region having a spherical bearing surface;

a bone fastening screw adapted to be received in the orifice, the bone fastening screw having a head with an essentially spherical surface adapted to bear against the spherical bearing surface;

a plug having a second thread adapted to cooperate with the first thread and further adapted to come into clamping contact with the head of the bone fastening screw through torque applied to the plug to hold the screw against the bearing surface in a desired angular position, thus creating a stiffness of assembly; and

a stiffness-attenuating material coupled to at least part of the screw head whereby stiffness of assembly between the link member and the bone fastening screw is reduced.

11. The device of claim 10 wherein the stiffness-attenuating material comprises at least one piece of flexible material interposed and compressed between the screw head and the plug.

12. The device of claim 11 wherein the stiffness-attenuating material is comprised of a plurality of flexible materials, each flexible material having different flexibilities so as to enable different degrees of stiffness attenuation between the link member and the bone fastening screw without varying the torque applied to the plug from one flexible material to another flexible material.

13. The device of claim 11 wherein the one piece of flexible material is an O-ring.

14. The device of claim 11 wherein the one piece of flexible material is a pellet.

15. The device of claim 10 wherein the stiffness-attenuating material comprises a thixotropic fluid interposed and compressed between the plug and the screw head.

16. The device of claim 10 wherein the stiffness-attenuating material comprises a surface coating suitable for reducing friction between the essentially spherical bearing surface and the complementary surface of the screw head.

17. The device of claim 16 wherein the surface coating is made by nitrogen ion bombardment.

18. A bone fixing device for use in osteosynthesis of the backbone, the device comprising:

a link member having a through orifice, the through orifice having a top region having a first thread and a bottom region;

a flexible O-ring in the shape of spherical bearing surface and located in the bottom region of the orifice;

a bone fastening screw adapted to be received in the orifice, the bone fastening screw having a head with an essentially spherical surface adapted to bear against the spherical bearing surface; and

a plug having a second thread adapted to cooperate with the first thread and further adapted to come into clamping contact with the head of the bone fastening screw through torque applied to the plug to hold the screw against the bearing surface in a desired angular position, thus creating a stiffness of assembly.

19. A bone fixing device for use in osteosynthesis of the backbone, the device comprising:

a link member having a through orifice, the through orifice having a top region having a first thread and a bottom region;

a cylindrical rod having a cylindrical circumference;

a rigid ring in the shape of spherical bearing surface and located in the bottom region of the orifice;

a bone fastening screw adapted to be received in the orifice, the bone fastening screw having a head with an essentially spherical surface adapted to bear against the spherical bearing surface;

a top-loading screw fixed about the cylindrical circumference of the cylindrical rod; and

a plug having a second thread adapted to cooperate with the first thread and further adapted to come into clamping contact with the head of the bone fastening screw through torque applied to the plug to hold the screw against the bearing surface in a desired angular position, thus creating a stiffness of assembly.

20. The device of claim **19** wherein the rigid ring is made of a material selected from the group comprising: ceramic-coated titanium alloys, titanium alloys treated by ion bombardment, and solid ceramics.

* * * * *

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United States Patent [19]

Navas

[11] Patent Number: 5,540,688

[45] Date f Patent: Jul. 30, 1996

[54] **INTERVERTEBRAL STABILIZATION DEVICE INCORPORATING DAMPERS**

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[73] Assignee: **Societe "PSI"**, Lyons, France

[21] Appl. No.: **207,259**

[22] Filed: **Mar. 8, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 888,130, May 26, 1992, abandoned.

[30] **Foreign Application Priority Data**

May 30, 1991 [FR] France 91 06695

[51] **Int. Cl.**[6] **A61F 5/04**; A61F 2/44

[52] **U.S. Cl.** **606/61**; A61F/5/04; A61F/2/44; 623/17; 606/72

[58] **Field of Search** 623/16, 17, 18; 606/61, 75

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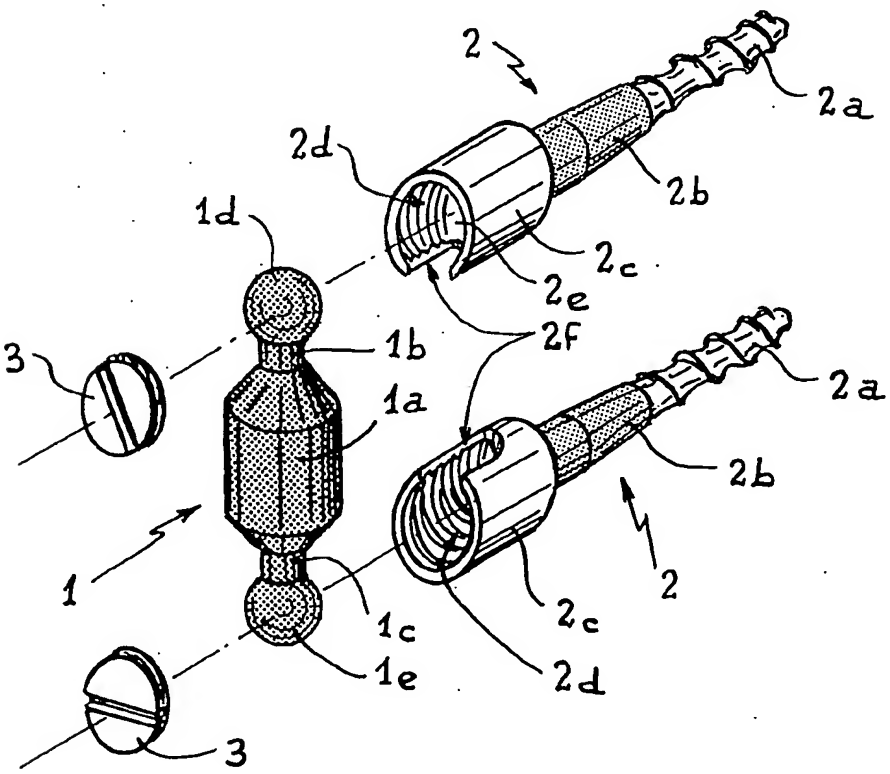
Primary Examiner—David J. Isabella
Attorney, Agent, or Firm—Dowell & Dowell

[57] **ABSTRACT**

An intervertebral stabilization device is disclosed, made in the form of a damper adapted to resist elastically, on the one hand, an elongation and, on the other hand, an axial compression without buckling, as well as of at least two implants anchored on two adjacent vertebrae.

20 Claims, 6 Drawing Sheets



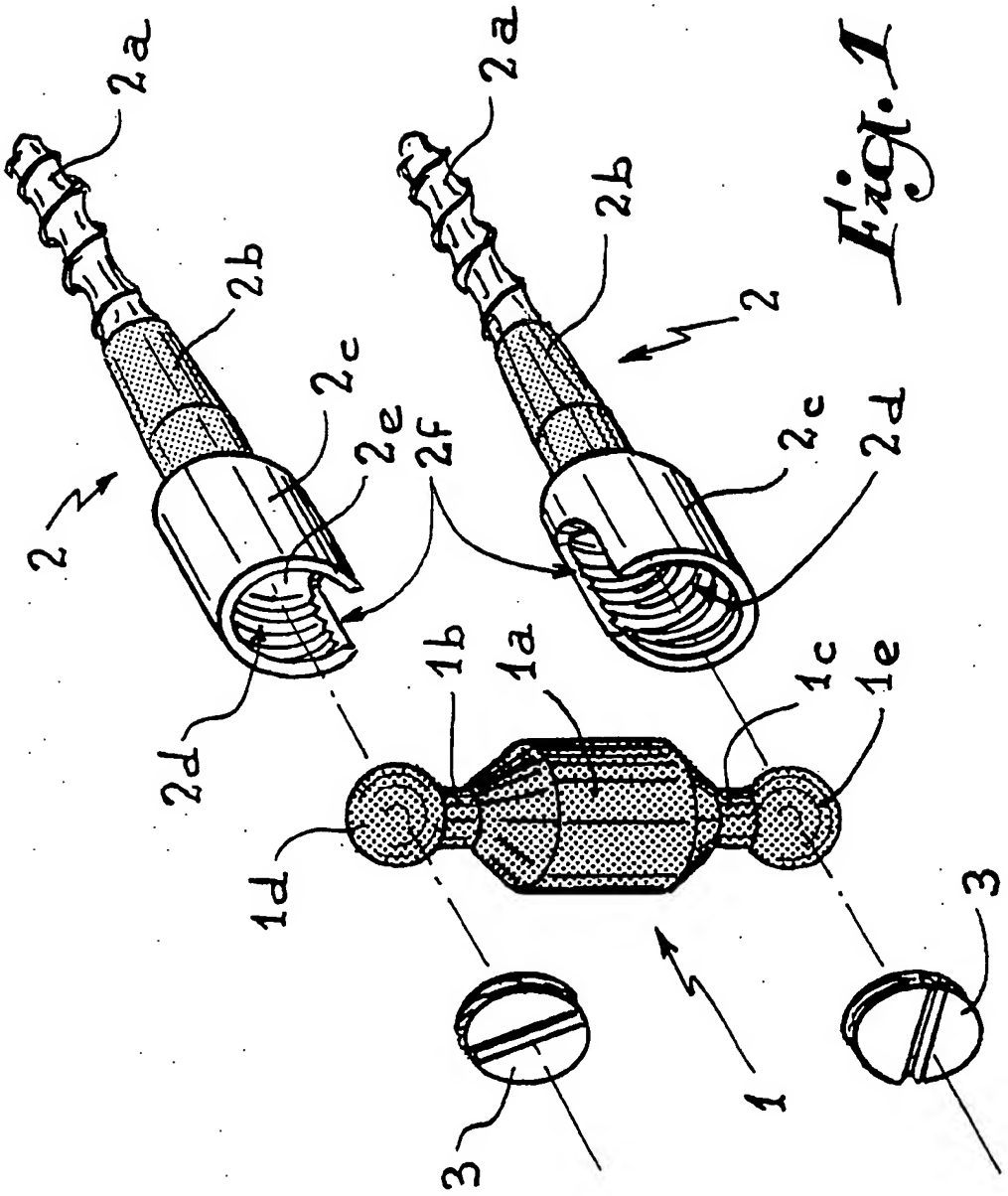


Fig. 1

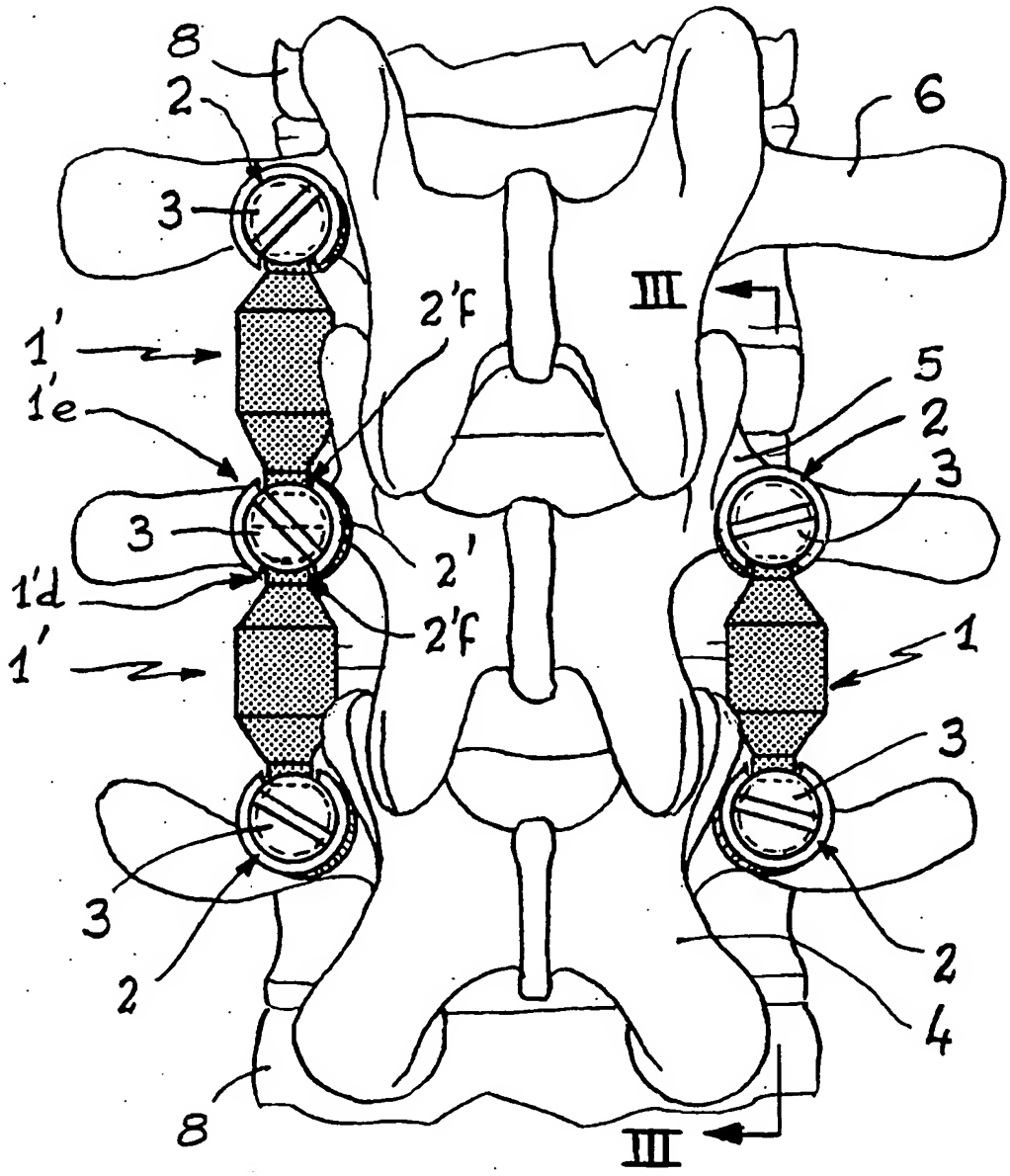


Fig. 2

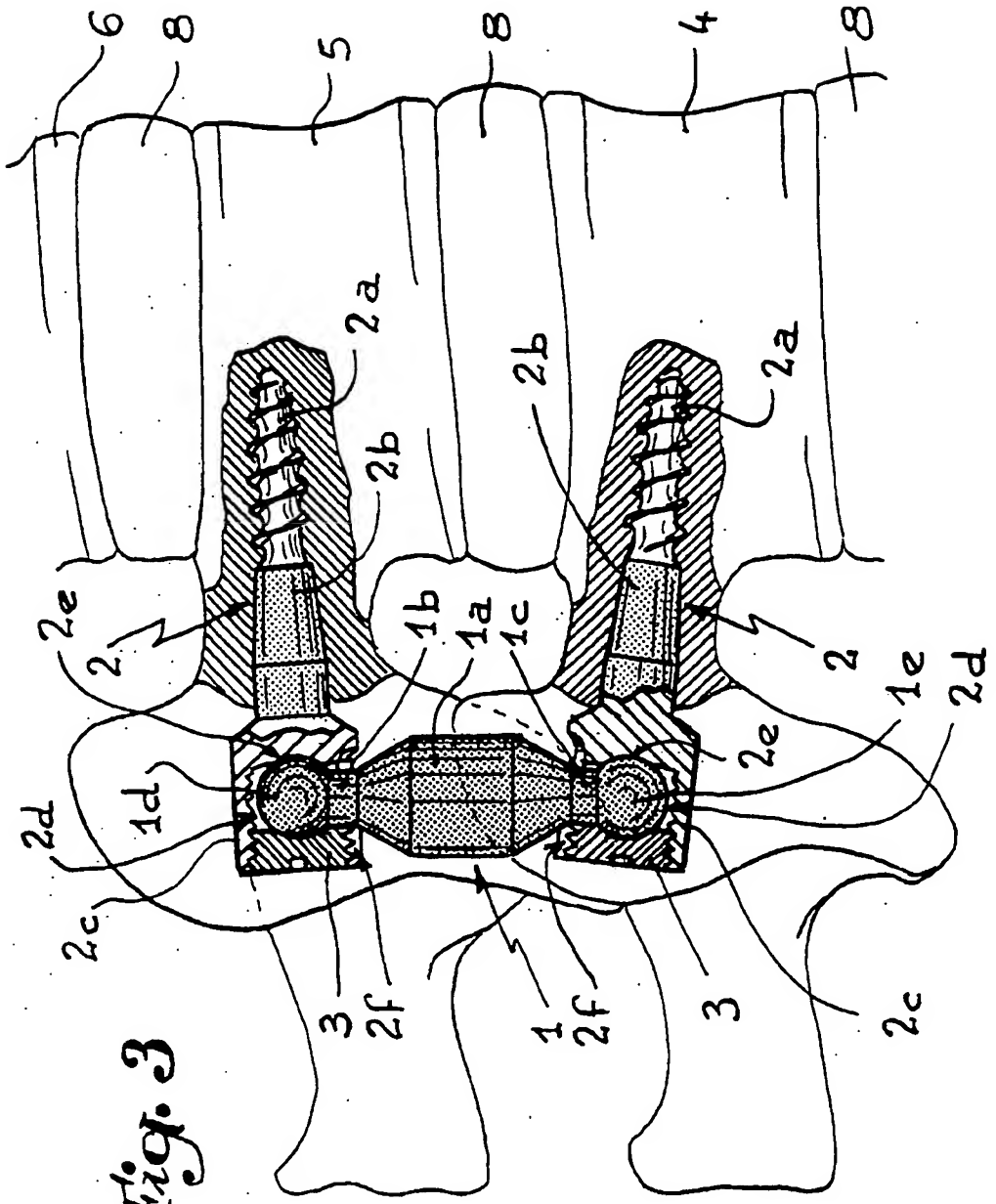


Fig. 3

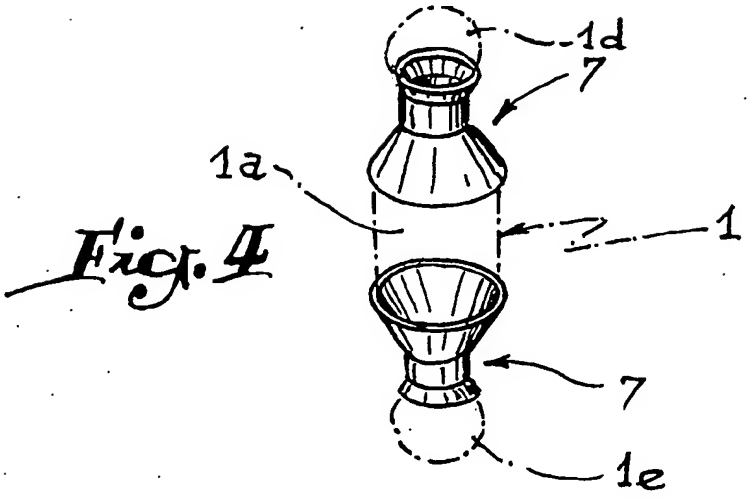
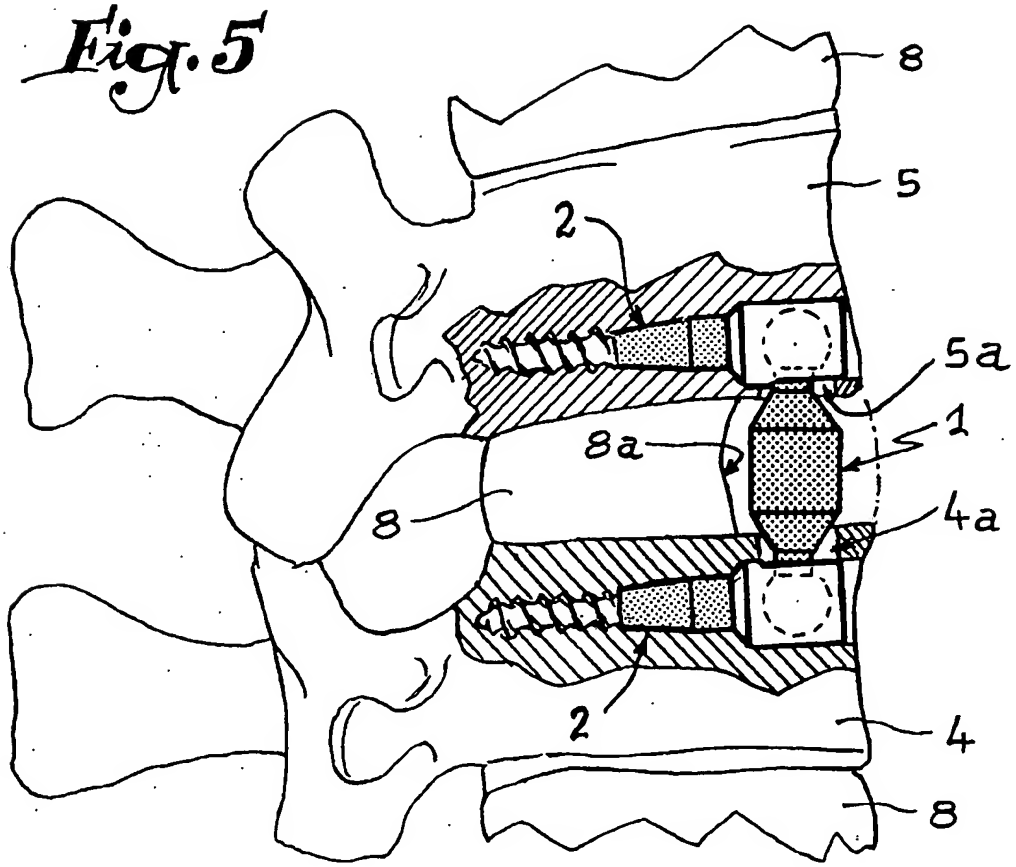


Fig. 4

Fig. 5



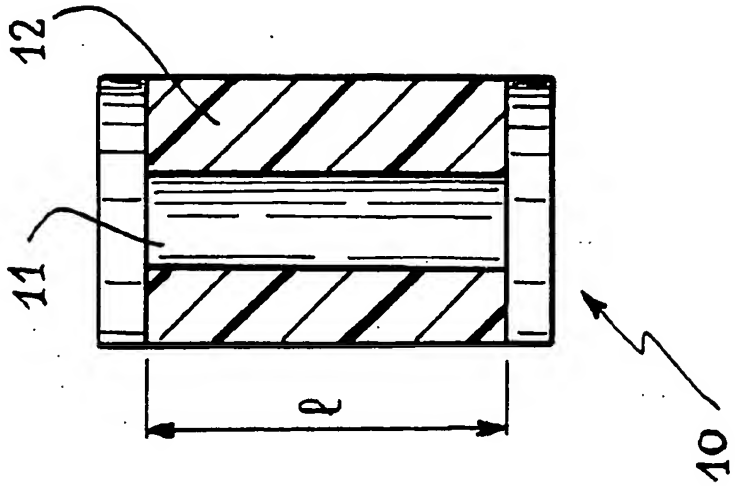


Fig. 6

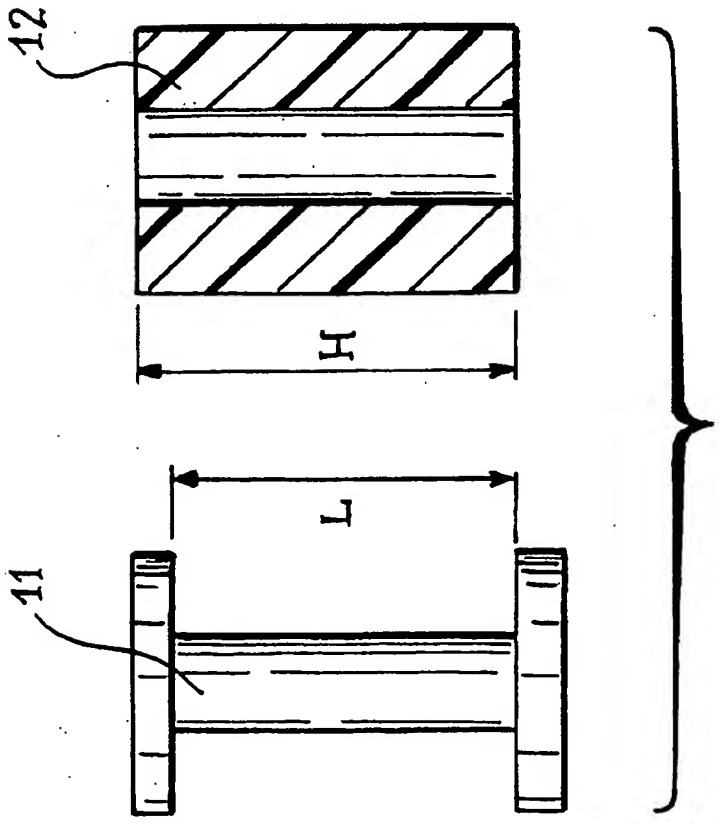


Fig. 7

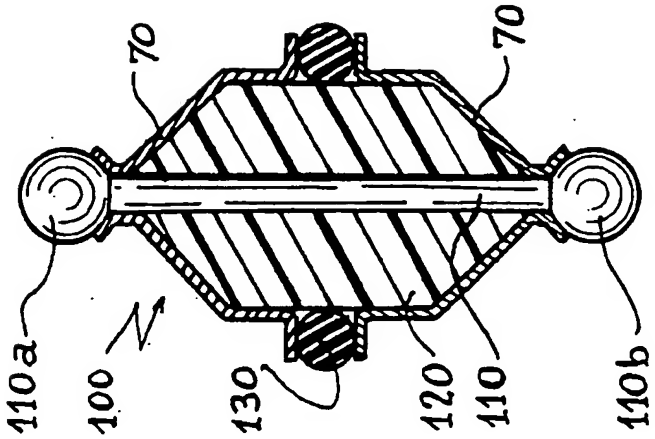


Fig. 10

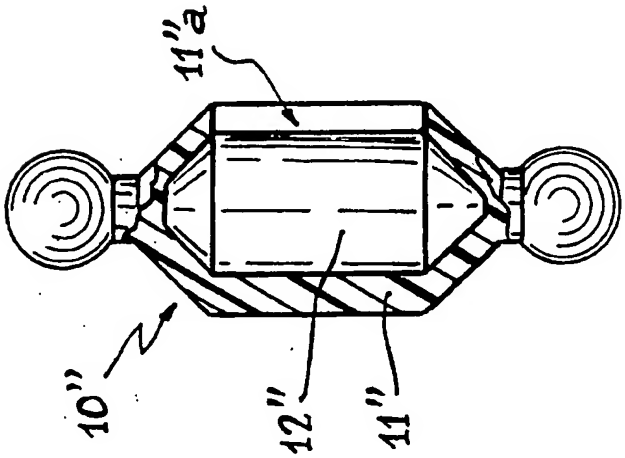


Fig. 9

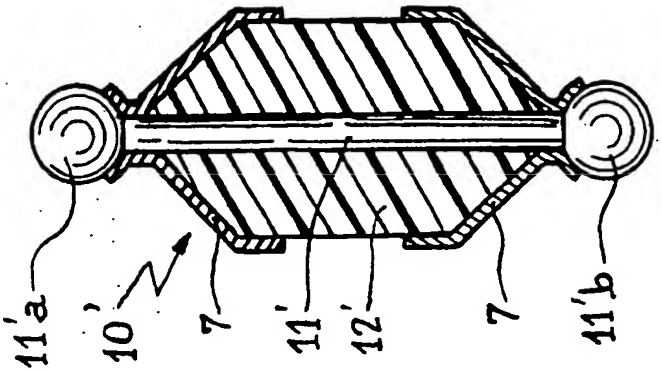


Fig. 8

INTERVERTEBRAL STABILIZATION DEVICE INCORPORATING DAMPERS

This application is a continuation of application Ser. No. 07/888,130, filed May 26, 1992, now abondoned.

BACKGROUND OF THE INVENTION

The present invention relates to intervertebral stabilization devices intended for maintaining at least two vertebrae, whose common disc is worn, in suitable relative position.

It is known that, in the course of ageing, the intervertebral discs risk wearing, with the result that the movements of the intervertebral articulation change, becoming abnormally more ample. The vertebrae may then move in excessive manner with respect to one another, causing permanent displacements as the vertebrae are badly positioned.

The intervertebral disc behaves more like a distributor of pressure or a three-dimensional coupler of movements than as a simple absorber of longitudinal loads.

The intervertebral movement is guided by the set of posterior articulations. The latter have only one degree of freedom; the two surfaces being able only to slide on each other.

During this movement, the disc deforms elastically, progressively braking the movement and dampening it completely at the end of amplitude.

The disc presents a visco-elastic quality. It progressively adapts by viscosity to a new anatomical relation. Consequently, the return movement is then taken over by a similar progressive damper, and this rapidly from its origin.

The set of the articular facets may be asymmetrical and consequently may create a three-dimensional movement coupling lateral bending and horizontal rotation.

This complex movement is itself coupled to the large movement of bending-extension. In complete bending as in complete extension, the amplitude of the combined movement (bending-rotation) becomes zero while it obtains a maximum amplitude in anatomical position, i.e. in the natural anatomical relation of the vertebrae when one is standing or when one is walking (in fact, in an intermediate position between bending and maximum extension).

The biological degradation of the disc disturbs these mechanics of coupled and dampened movements.

This evolution is a source of discomfort and of pain.

U.S. Pat. No. 4 743 260, for example, already proposes placing between at least two adjacent vertebrae a flexible stabilization device composed of two elements fixed to the vertebrae in question. The stabilization elements are made of a non-metallic material which is resistant but sufficiently flexible to allow at least a normal movement of the backbone.

The stabilization elements in question are made of a carbon-fiber-reinforced plastic material, with the result that they have a certain flexibility. However, this flexibility is limited to very small amplitudes in the sense of their curvatures, but no elasticity in traction or in compression.

It has thus been proposed to place a supple, non-elastic tie between two vertebrae to limit like a sudden brake, the movement in its amplitude in bending. At that stage, it behaves like a rigid system, transferring the mechanical stresses on the adjacent intervertebral articulations.

This comes back to the complications of mechanical overload as for arthrodeses or rigid metal assemblies.

Furthermore, the degenerative pathological movement between two vertebrae is not only a movement of exaggerated amplitude but also a subtle disorganzation of the three-dimensional coupling of different degrees of freedom.

A simple supple tie can but help, only insofar as it positions the two vertebrae in an extreme amplitude and therefore in extension.

The residual micro-movements possible due to the creeping of the tie are capable of contributing an elementary, rough adaptation with respect to functional needs. However, their existence clearly differentiates this fixation with respect to the rigid system (arthrodesis or metallic fixation).

It is an object of the improvements forming the subject matter of the present invention to produce devices capable of accompanying the ageing of the discs and which therefore constitute prostheses avoiding the drawbacks mentioned hereinabove.

It will be understood that the purpose of the proposed system is to make good in the most physiologically possible the shortcomings of the disc created by the biological and pathological conditions.

The system proposed aims at obtaining a new stability from an intervertebral position approaching the neutral position (between bending-extension).

In this position, the possibility of movements of the posterior articular surfaces is greater in particular in the sense of extension.

Furthermore, the asymmetrical work of the two posterior surfaces is possible.

The stability of the intervertebral articulation is then obtained due to the quality of damper of the device according to the invention.

The role of the invention is to accompany the movement of the articulation by limiting it slightly in bending and by avoiding abnormal displacements. Operating in parallel, while maintaining the vertebrae in extension with respect to one another, the invention avoids too much contact of the articular surfaces on one another. The system according to the invention also limits the closure of the lateral recess, consequently preventing the possible compression of the nerve root.

SUMMARY OF THE INVENTION

To that end, the invention comprises a damper adapted elastically to resist, elongation and axial compression. The damper is associated with at least two implants anchored on two adjacent vertebrae.

The damper is in the form of an elongated body provided with a bulged or enlarged central part joined by two necks to two enlarged ends cooperating with the implants.

In this way, the damper according to the invention may exert a distracting or compressive force, which enables it to act permanently on the poor intervertebral position.

In other words, the stabilization device according to the invention guides and limits the movement of the intervertebral articulation, while being capable of exerting permanent forces modifying the position of the vertebrae with respect to one another.

The stabilization device according to the invention is capable of damping the movement in bending and in extension and, consequently, of allowing asymmetrical work of the surfaces of the vertebrae while allowing the resultant three-dimensional coupled movement.

In this way, one approaches a complex and damped physiological movement.

Of course, one single device according to the invention, or several, may be used to join two adjacent vertebrae.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more readily understood on reading the following description with reference to the accompanying drawings, in which:

FIG. 1 is a view in perspective of the different elements constituting a stabilization device according to the invention.

FIG. 2 is a view from behind of three vertebrae associated with the stabilization devices according to the invention.

FIG. 3 is a section along III—III (FIG. 2). FIG. 4 is a view in perspective of two bushes adapted to cooperate with the necks of the damper of a device according to the invention.

FIG. 5 is a view similar to that of FIG. 3, but illustrating the assembly of a device according to the invention in anterior position.

FIG. 6 is a very schematic view in section of the principle of a damper in accordance with a variant embodiment of the invention.

FIG. 7 shows in section, in the free state, the two elements of the damper of FIG. 1.

FIGS. 8, 9 and 10 are longitudinal sections of three different embodiments of the damper illustrated in FIG. 6.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring now to the drawings, and firstly to FIG. 1, the device according to the invention essentially comprises a damper **1** made of a bio-compatible, elastic material and two implants **2** screwed in two adjacent vertebrae and whose free ends are associated with the two ends of the damper **1**.

It is observed that the damper **1** is made in the form of an elongated body provided with a bulged or enlarged central part **1***a* joined to two necks **1***b*, **1***c* to two bulbous ends **1***d*, **1***e*. In am advantageous embodiment of the preceding arrangement, the bulged part **1***a* may be provided to be of elliptic longitudinal section, while the two ends **1***d* and **1***c* each take the form of a sphere. Of course, the part **1***a* may be of cylindrical section with two truncated endpieces or in the form of two frustums of cone or may be asymmetrical in particular applications.

Each implant **1** includes a screw **2***a* adapted to be screwed in the pedicle of a vertebra or in any other location thereof. The screw **2***a* extends from a cylindrical body **2***b* which terminates in a hollow socket or receptical **2***c* of cylindrical shape with a tapped inner wall **2***d* and a concave bottom **2***e* presenting a shape complementary to that of half the end **1***d*, **1***e* of the damper. It is observed that the socket **2***c* is provided with a lateral notch **2***f* adapted to allow passage of the neck **1***b*, **1***c* of the damper **1** for positioning the damper with respect to the implants. Locking of the ends of the damper **1** is effected after they have been placed in the sockets **2***c* by screwing a threaded endpiece **3** inside the corresponding socket with respect to the tapped wall **2***d*. Of course, the base **3***a* of the endpiece **3** is provided to be concave and hemispherical, so as to cooperate exactly with the spherical ends **1***d*, **1***e* of the damper. FIGS. **2** and **3** illustrate the assembly of a device according to the invention with respect to two adjacent vertebrae **4** and **5** of a spine.

On the right-hand side of FIG. **2**, a device has been illustrated, comprising one damper **1** associated with two implants **2** each fastened to a vertebra **4**, **5**. The same assembly may be provided in the left-hand part. In addition, it is possible that three successive vertebrae **4**, **5**, **6** need stabilization. In that case, one of the implants **2'** comprises two diametrally opposite notches **2'***f*, while the ends of the two dampers **1'** each comprise one end **1'***d*, **1'***e*, truncated along a diametral plane of the sphere perpendicular to the longitudinal axis of the damper in order that the two truncated ends **1'***d*, **1'***e* may be retained in the socket of the implant **2'** (cf. the left-hand part of FIG. **2**).

FIG. **3** shows in very detailed manner the structure of the assembly of the ends of the damper with two implants. The hollow socket **2***c* with bellied concave base **2***e* is found again, as well as the endpiece **3** with bellied concave base **3***a* in order that the two spherical ends **1***c*, **1***d* of the damper **1** are suitably locked with respect to the implants **2**. Such locking makes it possible to create a sort of ball-joint articulation facilitating the movements of the spine.

As illustrated in FIG. **4**, the necks **1***b*, **1***c* of the damper **1** are advantageously protected by a bush **7** made of metal or any other rigid material and which ensures the mechanical quality of the relation between the damper and the implants. The bushes **7** may comprise on their inner faces notches which intervene actively, reducing mechanical efforts in the corresponding neck.

As illustrated in FIGS. **2** and **3**, the stabilization device according to the invention is positioned either on the posterior face or on the lateral face of the vertebrae. It may also be used at the front of the vertebral body, as illustrated in FIG. **5**.

In this mode of positioning, it goes without saying that the implants **2** must be disposed laterally outside the vessels or the device will be placed as illustrated in FIG. **5**, i.e. embedded in the vertebrae.

In that case, a slight resection of the intervertebral disc **8** is made to form a depression **8***a* therein. The implants **2** are driven deeply in the vertebra so that their socket **2***c* is embedded in the vertebra which is itself notched at **4***a*, **5***a* in order to allow passage of the two necks of the damper. It is thus ensured that the device does not interfere with the vessels located along the anterior face of the spine.

The dampers may be provided with different lengths varying from some millimeters with respect to one another so that the length of the damper can be adjusted to the anatomical pathology of the patient.

A stabilization system has thus been produced, making it possible to obtain a set of the residual intervertebral movements necessary for the elementary physiology of the spine, while eliminating the bad positions of the vertebrae and abnormal movements thereof.

Any appropriate material may be used for making the damper **1**, in particular a bio-compatible elastomer. A composite material may also be adopted, optimally responding to the two mechanical requirements of the damper, viz. the resistance to longitudinal traction and to a compression without buckling. The materials chosen may be of the same family or totally different.

The principle of the damper made of a composite material is illustrated in FIGS. **6** and **7**. The damper, referenced **10**, comprises two elements **11** and **12** both made of bio-compatible elastic materials. The first element **11** is in the form of a spool of which the distance between the flanges is referenced L in the free state. The second element, referenced **12**, takes the form of a tubular sleeve of height H in

the free state. Assembly of the damper consists in placing element 12 between the flanges of the element 11 after the latter has been elongated. Therefore, the element 11 compresses by its flanges the element 12 in the sense of compression, while the latter maintains element 11 in a pre-tensioned position. In this way, the length l of the sleeve after assembly and which corresponds to the distance between the flanges of element 12 is defined by the relation L<l<H.

In a first practical embodiment illustrated in FIG. 8, element 11' or core takes the form of dumb-bells, while element 12 is made in the form of a body 12' whose general shape is that of the centre of the damper 1 of FIGS. 1, 2 and 3.

In order to produce such a damper, the core 11' is made. The rod thereof is elongated elastically in the axial sense, then the body 12' is moulded on this core. After manufacture, the core 11'*a* is pre-tensioned, while the body 12' is pre-compressed. It will be noted that the core 11' and the body 12' are joined by means of two bushes 7 in the form of diabolos, the ends of the core 11' projecting beyond the ends; of the body 12', while the two spherical heads 11'*a*, 11'*b* of the core correspond to the spheres 1*d*, 1*e* of the damper 1.

In a second embodiment illustrated in FIG. 9, the damper referenced 10", comprises an elastic envelope 11" of which the outer shape corresponds to that of the damper 1, as well as a block of elastic material. 12". After manufacture, the envelope 11" which comprises a hollow inner cavity, is elongated so as to increase the height of its cavity in which the block 12" is introduced via a lateral opening 11"*a* or the like. The envelope 11" is consequently pre-tensioned in elongation, while the block 12" is pre-compressed by the action of the envelope.

Finally, in a practical embodiment illustrated in FIG. 10, the damper 100 comprises a body 120 which is mounted on an element 110 in the form of dumb-bells as already shown in FIG. 8. The element 110 and the body 120 are joined by means of two sleeves 70 in the form of diabolos of which one of their ends abuts against the spherical heads 110*a* and 110*b* of the element 110 corresponding to the spheres 1*d*, 1*e* of the damper 1. The other ends of the sleeves 70 are respectively curved towards the outside of the damper 100 in order to form a circular free space inside which is introduced an O-ring 130. This latter makes it possible to compensate the efforts of compression of the damper 100.

It is ascertained that the O-ring 130 may be made of a bio-compatible material similar to that of the body 12 so as to be able to resist the efforts of compression. The O-ring 30 and the dumb-bell shaped element 110 may be used together on the same damper or independently of each other depending on the stresses to be regulated.

The hardness of the elements composing the damper 10', 10" will be chosen so that, under the effect of the forces applied by the vertebrae, none of the elements resumes its dimensions in the free state.

In this way, whether the damper is subjected to a force of traction or to a force of compression, it still remains pre-stressed, so that the force which is applied thereto is always damped at some point within the amplitude of the movement imposed on the composite damper.

It must, moreover, be understood that the foregoing description has been given only by way of example and that it in no way limits the domain of the invention which would not be exceeded by replacing the details of execution described by any other equivalents.

What is claimed is:

1. An intervertebral stabilization device to stabilize the movement between at least two vertebrae of a patient's spine which are positioned on opposite sides of a spinal disc, said device comprising, two anchoring elements each having means to be anchored to adjacent (vertebrate) vertebrae and a free end, a dampening element for dampening elongation of the spine during either axial tension or compression thereof, and said dampening element configured to extend generally exteriorly of the spinal disc and between said free ends of said anchoring elements, said dampening element including opposite ends, and locking means for securing said opposite ends to said free ends of said anchoring elements so that said dampening element works against said free ends to dampen elongation of the spine during either axial tension or compression of the spine.

2. The device of claim 1, wherein said dampening element has an elongated body, said body having an enlarged central portion and said opposite (enlarged) ends being enlarged, and a reduced neck portion joining each of said enlarged ends to opposite ends of said central portion.

3. An intervertebral stabilization device for stabilizing the movement between at least two vertebrae which are positioned on opposite sides of a spinal disc, said device comprising: two anchoring elements each having means to be anchored to adjacent vertebrae, a dampening element configured to be positioned and extending between and connected to said anchoring elements, said dampening element having an elongated body, said body having a central portion and opposite enlarged ends, each anchoring element including a socket means at one end thereof for receiving one of said enlarged ends, each of said socket means having a concave bottom surface shaped for close cooperation with said enlarged ends, securing means for retaining said enlarged ends, within said socket means, and said dampening element capable of resisting elastic elongation during either axial tension or compression of the spine.

4. The device of claim 3, wherein said socket means includes a tapped hole and a notch which opens laterally thereof, and said securing means includes a threaded end piece having a hemispherical base, said end piece being threadingly received within said tapped hole.

5. The device of claim 4, wherein said socket means includes two generally opposing notches therein, and at least one of the enlarged ends of said dampening element is hemispherical in configuration.

6. The device of claim 4, including a reduced neck portion between each of said enlarged ends and said central position, and a rigid sleeve means surrounding each of said reduced neck portions of said dampening element.

7. The device of claim 6, wherein the dampening element is made of a bio-compatible elastomer.

8. The device of claim 6, wherein the dampening element is made of two material components.

9. The device of claim 6, wherein said central portion of said elongated body has an elliptical shape in longitudinal cross-section.

10. The device of claim 6, wherein said central portion of said elongated body is asymmetrical.

11. The device of claim 8, wherein a first of said material components is pre-stressed in extension and the other of said material components is pre-stressed in compression.

12. The device of claim 11, wherein said first material component is in the form of a dumb-bell having a central rod portion and outer enlarged portions and said other material component is in the form of a sleeve which surrounds said rod portion and which sleeve is placed in compression by said outer enlarged portions.

13. The device of claim 11, in which said first material portion is in the form of an elastic envelope defining a cavity therein and said other material component is in the form of a block of elastic material placed in compression within said envelope.

14. The device of claim 11, in which said first material component includes a central element, said second material component being in the form of a sleeve surrounding said central element, a pair of opposing sleeve means surrounding said sleeve and extending inwardly toward one another and forming an annular space therebetween, and an O-ring means positioned within said annular space.

15. The device of claim 14, wherein the O-ring is made of a bio-compatible material which is resistant to compressive forces.

16. The device of claim 1, wherein the dampening element is made of two material components.

17. The device of claim 16, wherein a first of said material components is pre-stressed in extension and the other of said material components is prestressed in compression.

18. The device of claim 17, wherein said first material component is in the form of a dumb-bell having a central rod portion and outer enlarged portions forming said opposite ends of said dampening element, and said other material component is in the form of a sleeve which surrounds said rod portion and which sleeve is placed in compression by said outer enlarged portions.

19. The device of claim 17, in which said first material portion is in the form of an elastic envelope defining a cavity therein and said other material component is in the form of a block of elastic material placed in compression within said envelope.

20. The device of claim 17, in which said first material component includes a central element, said second material component being in the form of a sleeve surrounding said central element, a pair of opposing sleeve means surrounding said sleeve and extending inwardly toward one another and forming an annular space therebetween, and an O-ring means positioned within said annular space.

* * * * *

US005425779A

United States Patent [19]

Schlosser et al.

[11] Patent Number: 5,425,779

[45] Date of Patent: Jun. 20, 1995

[54] **PROSTHETIC IMPLANT FOR JOINT STRUCTURES**

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[21] Appl. No.: **203,860**

[22] Filed: **Mar. 1, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 926,043, Aug. 5, 1992, abandoned.

[51] **Int. Cl.**[6] **A61F 2/34**

[52] **U.S. Cl.** **623/23**

[58] **Field of Search** 623/22, 23, 18

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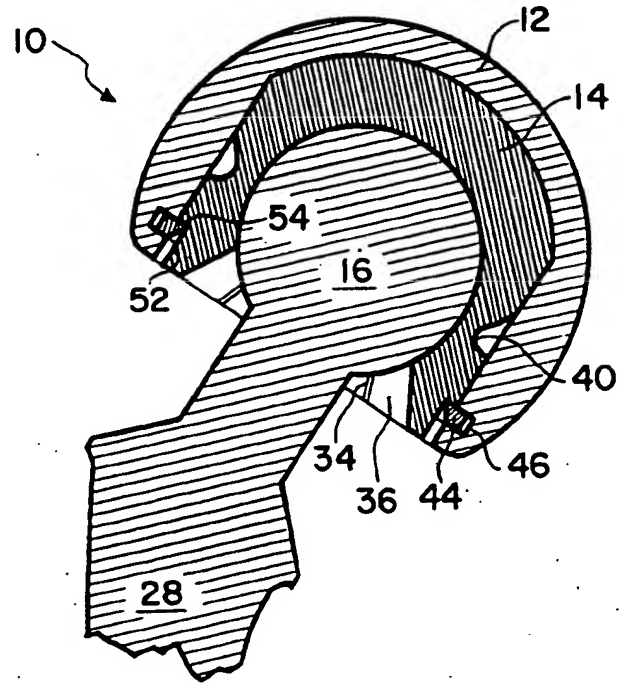
[57] **ABSTRACT**

A prosthetic implant for joint structures includes a shell, a head adapted to be secured to a bone leading to the joint structure in which the implant is to be used, an insert member adapted to be received in the shell and also adapted to receive the head, and a locking arrangement associated with the shell. The locking arrangement is adapted for releasably locking the insert member and head received therein in a receptacle in the shell. The locking arrangement preferably includes a ring of resilient material having an opening along part of its circumference for enabling the ring to resiliently expand and collapse. The ring is received in a groove inside the shell receptacle. As the insert member and head received therein are inserted into the shell, the ring expands into the groove allowing the insert member to pass. Once the insert member is fully received in the shell the ring snaps back to contact the insert member and retain it in the shell.

12 Claims, 2 Drawing Sheets



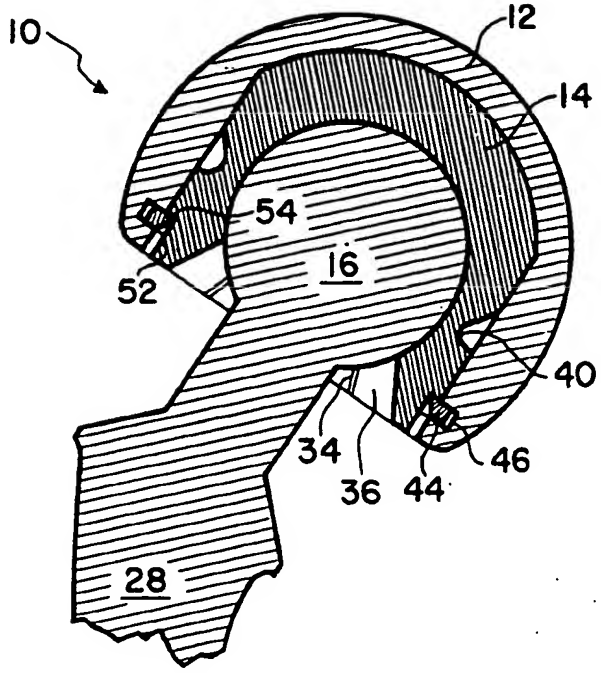


FIG. 3

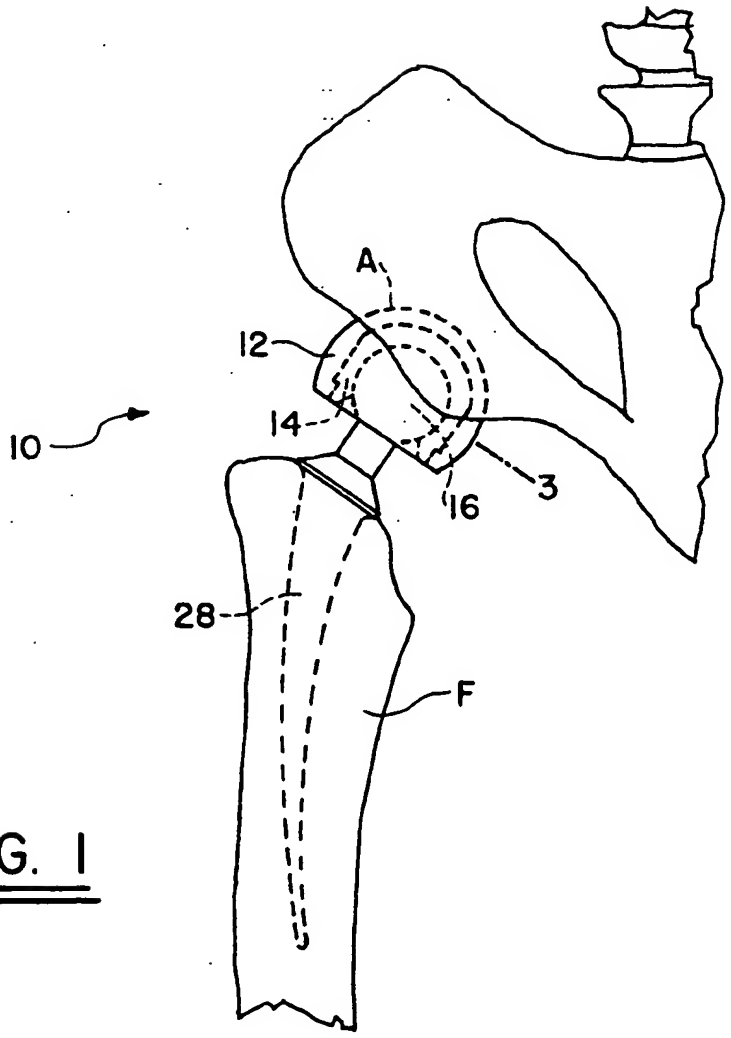


FIG. 1

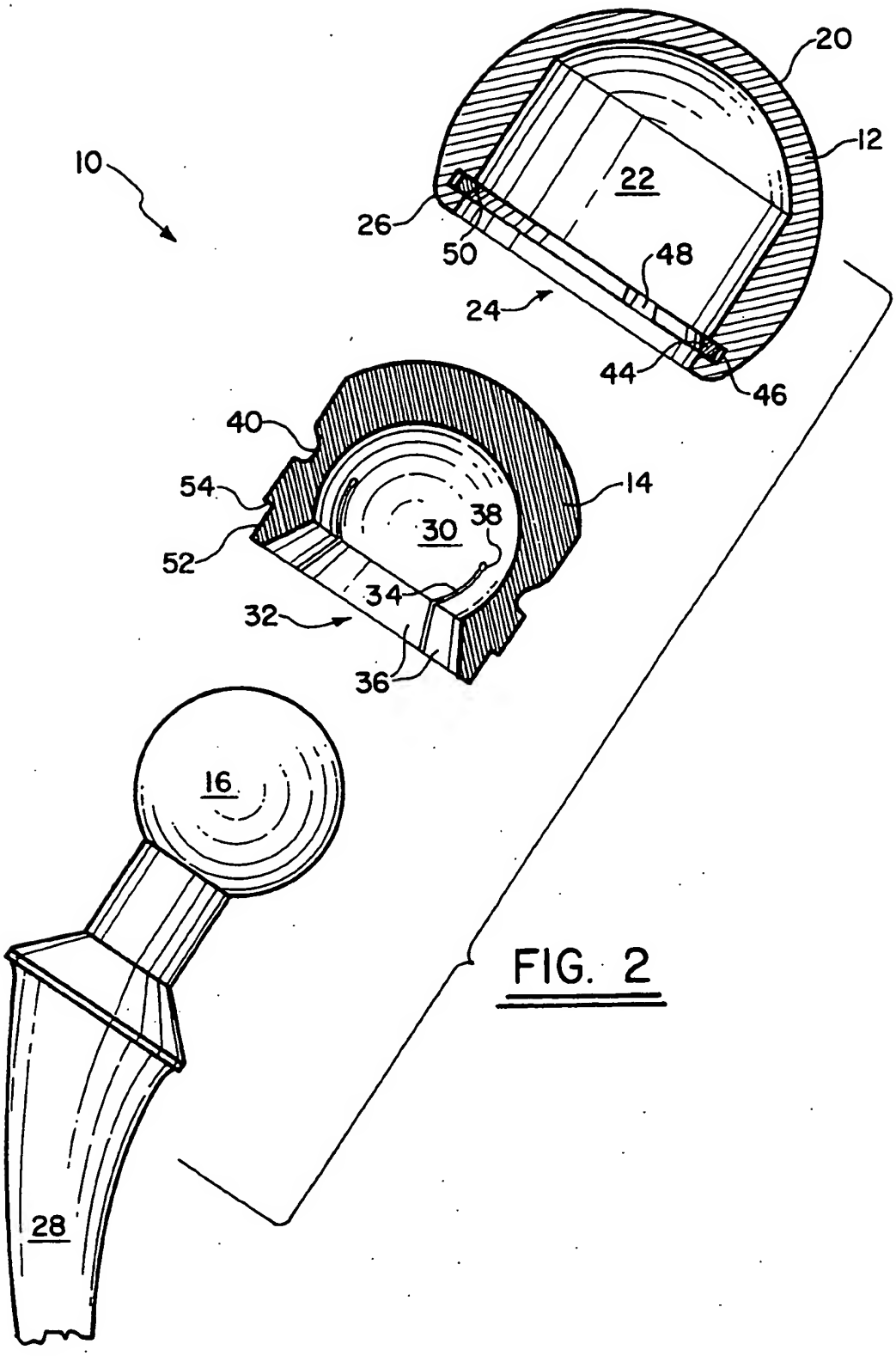


FIG. 2

PROSTHETIC IMPLANT FOR JOINT STRUCTURES

This application is a continuation of application Ser. No. 07/926,043 filed Aug. 5, 1992 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to prosthetic implants for joint structures and particularly to a prosthetic implant structure and assembly method for arthroplasty involving ball and socket type joints.

Arthroplasty or joint replacement for ball and socket type joints includes providing an implant to replace the natural anatomic ball or head of the joint. Prosthetic implants for ball and socket type joints are classified as either unipolar or bipolar. A unipolar implant includes simply a head adapted to replace the ball structure of the natural joint and to articulate with the anatomic socket structure. Bipolar implants provide for articulation within the implant itself in addition to articulation with the anatomic socket structure. The added articulation within the implant structure reduces wear on the natural socket structure and provides better range of motion and freedom of movement in the joint.

Bipolar implants for ball and socket type joint structures such as the hip joint, for example, include a head or ball, a shell adapted to be received in the anatomic socket structure, and a receptacle in the shell. An insert member is commonly received in the shell receptacle and the implant head is adapted to be received directly in the insert member. In the case of a hip joint bipolar prosthesis, the implant head is adapted to be attached to the top of the femur after the natural femur head is resected. The implant head articulates with the insert in the shell and the shell articulates with the anatomic socket or acetabulum.

The manner in which the several components of a bipolar prosthetic implant are assembled is critical to the functioning of the implant. The implant head should be easily removable from the insert member and shell yet must be retained in the shell securely with minimal play so that the implant head freely articulates in the insert. To enhance the flexibility of the surgical implantation procedure, the implant should also be adapted for relatively quick assembly and disassembly with a minimum of small parts.

Prior prosthetic implants for ball and socket type joints fail to meet one or more of these requirements. For example, U.S. Pat. No. 3,863,473 to AVERILL discloses a prosthetic hip joint implant that uses a tab formed on the insert member and a cooperating groove on the inner surface of the shell to retain the insert member in the shell. This tab arrangement, however, requires that the tab deflect inwardly as the insert member is placed in the shell. When the tab snaps outwardly in the groove formed in the shell, the arm on which the tab is formed also moves outwardly and leaves excessive play between the head and the insert member.

The implant structure shown in U.S. Pat. No. 4,718,918 to KENNA retains the insert member in the shell with a lip formed on the inside surface of the shell and a cooperating groove formed on the outside surface of the insert. This locking or retaining arrangement results in either play between the insert member and the head received therein or play between the insert member and the shell. The retaining arrangement also makes it difficult to remove the insert member once it is connected with the shell.

Another type of prosthetic hip joint implant is shown in U.S. Pat. No. 4,241,463 to KHOVAYLO. This patent is directed to a prosthetic implant that retains the insert member in the shell with a rigid lip on the inside of the shell and an groove formed in the insert similarly to the KENNA patent. However, KHOVAYLO uses a retaining slip ring within the insert member itself to retain the head within the insert member. The space required for the ring in the insert member greatly reduces the bearing surface available for the head, and results in some degree of play between the insert member and the head.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a prosthetic implant for joint structures that overcomes the above-described problems and others associated with prior implants. Another object of the invention to provide a method for assembling a prosthetic ball and socket type implant to overcome the above-described problems.

In order to accomplish these objects, a prosthetic implant embodying the principles of the invention includes a unique locking arrangement for locking the elements of a bipolar ball and socket type prosthetic implant together. The implant includes a shell, a head, and an insert member. The head is adapted to be received in a head receptacle formed in the insert member and the insert member is adapted to be received with the head therein in an insert receptacle formed in the shell. The locking arrangement includes locking means for releasably but securely locking the insert member in the shell while minimizing play between the insert member and inserted head and providing maximum bearing surface area for the head.

The locking means preferably includes a member that is adapted to extend into the insert receptacle in the shell in a locked position and to retract from the shell insert receptacle sufficiently to allow the insert member to be inserted into the insert receptacle. Once the insert member is received in the shell insert receptacle in a fully received position, the locking means is adapted to extend again into the insert receptacle to catch on a portion of the insert member and prevent the insert member from being removed from its fully received position in the shell insert receptacle.

In the preferred form of the invention the locking means comprises a locking ring mounted in an annular groove formed in the shell insert receptacle. The locking ring is made of a resilient material and includes an opening or split along part of its circumference so that it may be collapsed and placed in the annular groove. The resiliency of the locking ring material also enables the ring to retract as the insert member is inserted into the insert receptacle, and then spring back to retain the insert member in place. Also, a beveled edge is preferably formed on the inside edge of the locking ring. This beveled inside edge enables the ring to be expanded with a tool inserted into an annular space between the shell and the insert member so that the insert member may be easily removed from the shell.

According to the method of the invention, the head is first positioned within the head receptacle in the insert member. The opening to the head receptacle in the insert member preferably includes resilient means for expanding to receive the commonly spherically-shaped head and then spring back to retain the head in the

insert member. With the head received in the insert member and the locking ring received in the annular groove of the shell, the method continues with the step f inserting the insert member into the shell insert receptacle. In the preferred form of the invention, contact between the insert member and the locking ring causes the ring to expand and retract from the insert receptacle to allow the insert member to pass. Finally, when the insert member reaches the fully received position in the shell, the locking ring resiliently springs back into the insert receptacle to catch on a step or other feature formed on the insert member to retain the insert member in the fully received position.

The prosthetic implant locking arrangement and component assembly method according to the invention provides several important advantages. First, the locking means does not require that a part of the insert member move outwardly once inserted into the shell to contact and catch on a portion of the shell. Thus the present invention avoids the play between the head and insert member that accompanies any outward movement by the insert member after or as it is inserted into a shell. The locking arrangement also allows close tolerance between the insert member and the shell and avoids play there between. The present locking arrangement additionally enables the insert member to provide the maximum bearing surface area for the head. Furthermore, since the locking ring can be manually collapsed, the insert member may be removed from the shell without having to exert a substantial pulling force on the shell.

These and other objects, advantages, and features of the invention will be apparent from the following description of the preferred embodiments, considered along with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial perspective view illustrating a prosthetic implant embodying the principles of the invention applied to a hip joint.

FIG. 2 is an isolated partial longitudinal cross sectional view of the implant in FIG. 1 in a partially unassembled condition.

FIG. 3 is a partial longitudinal cross sectional view similar to FIG. 2 but with the implant in a fully assembled condition.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1 through 3 illustrate the preferred form of prosthetic implant 10 embodying the principles of the invention. As best shown in FIG. 1, the implant 10 is adapted particularly for replacing an anatomical hip joint. The terminology used in the following description will therefore refer particularly to the anatomical structure in and around the hip joint. However, those skilled in the art will readily appreciate that a prosthetic implant embodying the principles of the invention may be used in other ball and socket type joint structures such as the shoulder joint for example.

The illustrated form of the invention includes a shell 12, an insert member 14, and an implant head or ball 16. The implant head 16 is adapted to be connected to the top of the femur F by suitable means as shown in FIG. 1 and is also adapted to be received in the insert member 14. The insert member 14 with the implant head 16 received therein is adapted to be received in the shell 12 and the shell is placed in the hip socket or acetabulum A and is held in place by tendons and ligaments (not shown).

The shell 12 is made from a biologically compatible material such as a cobalt-chromium-molybdenum alloy or titanium alloy and includes a substantially spherical outer bearing surface 20. The outer bearing surface 20 is highly polished to allow the shell to easily articulate in the acetabular socket A. An insert receptacle 22 is formed in the shell 12 with an insert receptacle opening 24 for receiving the insert member 14. The insert receptacle 22 has a generally cylindrical cross-sectional shape with a concave end opposite the end in which the insert receptacle opening 24 is formed. The shell 12 also includes a well rounded lower edge 26 to prevent abrasion of soft tissue adjacent to the implant 10 and to reduce the possibility of catching on any portion of the acetabulum A as the shell articulates therewith.

The head or ball 16 shown in FIGS. 2 and 3 is generally spherical in shape. A stem 28 is connected to the head 16 and is adapted to be received in the central canal of the femur F as shown in FIG. 1 to secure the head to the femur. The head 16 and stem 28 may be modular or integrally formed as shown in the figures and are both made of a suitable biologically compatible material similar to the shell 12. As with the shell 12 the head 16 is highly polished to minimize friction as it articulates with the insert member 14.

The insert member 14 is adapted to fit within the insert receptacle 22 of the shell 12 with minimum tolerance and therefore preferably has an outer shape that conforms to the shape of the insert receptacle 22. In the illustrated form of the invention, the insert member 14 has a generally cylindrical outer cross-sectional shape with a convex end adapted to abut the concave surface within the insert receptacle 22 when the insert member is in the fully received position shown in FIG. 3. A head receptacle 30 with a receptacle opening 32 thereto is formed in the insert member 14 for receiving the head 16. The head receptacle surface forms a bearing surface for the head 16 and is therefore preferably spherical in shape to match the shape of the head. Since the insert member 14 forms a bearing surface for the head 16 and is preferably resilient as discussed below, the preferred insert member is made of ultra high molecular weight polyethylene (UHMWPE).

At the end of the insert member 14 in which the head receptacle opening 32 is located, a series of radial slots 34 are spaced out at different angular orientations about the center longitudinal axis of the insert member forming a series of arms 36 there between. The slots 34 extend approximately one-half of the longitudinal dimension of the insert member 14 and each slot ends in an enlarged stress relief opening 38. A circumferential groove 40 is formed on the outer surface of the insert member 14 at a position generally coinciding with the ends of the slots 34. The groove 40 creates a reduced cross-section area at the base of each arm 36 and this reduced cross-section area allows the arms to flex outwardly to accept the head 16 in the head receptacle 30. The resiliency of the material from which the insert member 14 is formed causes the arms to return to a relaxed position once the head 16 is fully received in the head receptacle 30 and retain the head therein.

The prosthetic implant 10 according to the invention also includes locking means for locking the insert member 14 and head 16 received therein in the shell insert receptacle 22. The locking means in this form of the invention comprises a locking ring 44 adapted to fit in

an annular groove r shell locking feature 46 formed on the wall of the shell insert receptacle 22 as shown in FIGS. 2 and 3. The locking ring 44 includes an opening 48 along a porti n f its circumference and is made of a resilient material such as UHMWPE similar to the insert member 14. The resiliency of the material and the opening or split 48 allows the locking ring 44 to collapse to a decreased diameter and to expand to an increased diameter and in each case to return to a relaxed position and diameter. Also, the preferred locking ring 44 includes a bevel on its inside surface 50. When the locking ring 44 is properly positioned in the groove 46, the bevel surface 50 forms a frustoconical shape with the larger diameter end of the shape facing toward the insert receptacle opening 24 of the shell 12.

Referring particularly to FIG. 2, the locking ring 44 extends into the insert receptacle 22 when in a relaxed condition in the annular groove 46. When the insert member 14 with the head 16 received therein is inserted into the shell insert receptacle 22 through the insert receptacle opening 24, contact between the insert member and the locking ring 44 expands the ring and causes the ring to retract substantially from the insert receptacle. When the insert member 14 reaches a fully received position in the shell in which the longitudinal axes of the insert receptacle and the head receptacle are generally aligned, as shown in FIG. 3, a reduced diameter section 52 of the insert member aligns with the annular groove 46 and locking ring 44. This reduced diameter feature 52 on the insert member 14 allows the ring 44 to extend back to its relaxed shape and extend into the insert receptacle 22 to contact a step or insert member locking feature 54 formed by the reduced diameter section 52 on the insert member. This contact with the step 54 on the insert member 14 provides a positive lock to maintain the insert member in the fully received position.

Once in the fully received and locked position, the insert member 14 and head 16 can be removed only by expanding the ring 44 to again retract the ring from the insert receptacle 22 sufficiently to clear the step 54. Expanding the ring 44 can be accomplished easily by inserting a tool (not shown) into the annulus formed between the reduced diameter section 52 of the insert member 14 and the wall of the insert receptacle 22 in a direction substantially parallel to the longitudinal axis of the insert receptacle to contact the beveled surface 50 on the locking ring. Contact on the beveled surface 50 of the locking ring 44 applies an outward force component to expand the ring past the step 54 or other feature at which point the insert member 14 and head 16 received therein may freely slide out of the shell insert receptacle 22.

The prosthetic implant 10 embodying the principles of the invention has a number of advantages over prior implants for ball and socket type joints. First, when the insert member 14 is received in the fully received position shown in FIG. 3, the arms 36 on the insert member are constrained by the shell and can not flex outwardly. Thus the head 16 is securely locked in place but is free to articulate with the insert member 14. Thus the connection between the implant components is very strong yet the implant 10 can be disassembled easily simply by expanding the locking ring 44 as described above. Also, the locking mechanism does not interfere with the connection between the head 16 and insert member 14 and allows the insert member to provide a maximum bearing surface area for the head. Additionally, since the insert member 14 does not have to change outer cross-sectional shape to perform any locking function, the insert member may be designed with minimal tolerance with the insert receptacle 22 of the shell 12 and with the head 16. Furthermore, the implant 10 and locking mechanism comprises minimal parts and is easily and quickly assembled and disassembled during the surgical implantation procedure.

Pursuant to the method of assembling the prosthetic implant 10 according to the invention, the head 16 is first inserted into the head receptacle 30 in the insert member 14. With the head 16 received and retained in the insert member 14, the insert member is then pushed into the shell insert receptacle 22 through the insert receptacle opening 24. The method continues with the step of retracting the locking means, in the illustrated case the locking ring 44, substantially from the insert receptacle 22 to allow the insert member 14 to pass further into the insert receptacle. Once the insert member 14 is in the fully received position in the shell 12, the method includes extending the locking member 44 back into the insert receptacle 22 to contact the step 54 formed on the insert member thereby providing a positive lock to retain the insert member in the shell 12.

In the preferred form of the invention shown in the figures, the method also includes the step of continuously biasing the locking ring 44 to the relaxed position extending into the insert receptacle 22. The preferred method also includes maintaining the outer cross-sectional shape of the insert member 14 constant as the insert member is inserted into the shell receptacle 22. Maintaining a constant outer cross-sectional shape in the insert member 14 reduces the possibility of play between the insert member and head 16.

The above described preferred embodiments are intended to illustrate the principles of the invention, but not to limit the scope of the invention. Various other embodiments and modifications to these preferred embodiments may be made by those skilled in the art without departing from the scope of the following claims. For example, the insert, locking ring, and shell may be made of any suitable material. Also, the locking means need not be a split ring nor be continuously biased inwardly toward the insert receptacle 22. The locking means could alternatively be a member mounted on the shell 12 in position to be manually extended and retracted into and from the shell receptacle 22 to provide the locking function. Also, the locking means could be associated with the insert member rather than the shell. Furthermore, although the illustrated insert with resilient arms 36 is preferred for its ease of manufacture and one-piece design, any suitable structure may be used to retain the head 16 in and insert member.

We claim:

1. A prosthetic implant for joint structures, the implant comprising:

(a) a shell having an insert receptacle with an insert receptacle opening thereto and a longitudinal insert receptacle axis;

(b) an insert member having a head receptacle and head receptacle opening adapted for receiving a head member associated with the implant, the insert member being adapted to be received in a received position in the insert receptacle of the shell wherein the head receptacle opening is substantially aligned with the insert receptacle opening and the longitudinal insert receptacle axis is substantially aligned with a longitudinal head receptacle axis;

(c) a locking ring positioned around a circumference of the insert receptacle transverse to the longitudinal insert receptacle axis, the locking ring f r extending between and contacting an insert member locking feature on the insert member and a shell locking feature on the shell when in a locked position with the insert member in the received position in the insert receptacle, thereby retaining the insert member in the received position in the shell, the locking ring also being capable of resiliently moving to a retracted position in which it does not simultaneously contact the insert member locking feature and the shell locking feature thereby enabling the insert member to be removed from the shell; and

(d) a beveled surface formed on the locking ring and extending at an acute angle with respect to the longitudinal insert receptacle axis when the locking ring is in the locked position and the insert member is in the received position in the shell, the beveled surface for moving the locking ring from said locked position to the retracted position in response to a retracting force applied to the beveled surface in a direction substantially parallel to the longitudinal insert receptacle axis.

2. The implant of claim 1 wherein:

(a) the head receptacle of the insert member includes a head bearing surface that comprises a portion of a sphere greater than a hemisphere.

3. In a joint structure prosthetic implant including a shell having an insert receptacle with an insert receptacle opening thereto and a longitudinal insert receptacle axis, a substantially spherical head adapted to be secured to a bone leading to a joint in which the implant is to be used, and an insert member having a head receptacle and a head receptacle opening thereto for receiving the head and providing a bearing surface therefore, and wherein the insert member is adapted to be received in a received position in the insert receptacle of the shell through the insert receptacle opening so that the head receptacle opening is generally aligned with the insert receptacle opening, the improvement comprising:

(a) a locking ring positioned around a circumference of the insert receptacle transverse to the longitudinal insert receptacle axis, the locking ring for extending between and contacting an insert member locking feature on the insert member and a shell locking feature on the shell when in a locked position with the insert member in the received position in the insert receptacle, thereby retaining the insert member in the received position in the shell, the locking ring also being capable of resiliently moving to a retracted position in which it does not simultaneously contact the insert member locking feature and the shell locking feature thereby enabling the insert member to be removed from the shell; and

(b) a beveled surface formed on the locking ring and extending at an acute angle with respect to the longitudinal insert receptacle axis when the locking ring is in the locked position and the insert member is in the received position in the shell, the beveled surface for moving the locking ring from said locked positi n to the retracted position in response to a retracting force applied to the beveled surface in a direction substantially parallel to the longitudinal insert receptacle axis.

4. The implant of claim 1 wherein the locking ring comprises:

(a) a ring of resilient material having an opening along part of its circumference for enabling the ring to expand and collapse, the ring being received in an inwardly directed annular groove formed in the shell.

5. The implant of claim 4 wherein:

(a) the ring includes an inside edge adapted to contact a circumferential step on the insert member when the ring is in the locked position and the insert member is in the received position in the shell insert receptacle.

6. The implant of claim 5 wherein:

(a) the beveled surface on the locking ring forms a substantially frustoconical shape with a larger diameter end of the shape facing toward the insert receptacle opening of the shell.

7. The implant of claim 1 wherein:

(a) the insert member has an outer transverse cross-sectional size and shape that remains substantially constant as the insert member is inserted into the insert receptacle of the shell.

8. The implant of claim 2 wherein the insert member includes:

(a) a series of longitudinally extending arms spaced out around its periphery at an end of the insert member in which the head receptacle opening is formed, the arms being adapted to bend outwardly to increase the size of the head receptacle opening sufficiently to allow the head member to be inserted therethrough and then resiliently bend back inwardly to retain the head member in the head receptacle.

9. The implant of claim 3 wherein the locking ring comprises:

(a) a ring of resilient material having an opening along part of its circumference for enabling the ring to expand and collapse, the ring being received in an inwardly directed annular groove formed in the shell.

10. The implant of claim 9 wherein:

(a) the ring includes an inside edge adapted to contact the insert member locking feature when the insert member is in the received position in the insert receptacle of the shell and the ring is in the locked position.

11. The implant of claim 10 wherein:

(a) the beveled surface on the locking ring forms a substantially frustoconical shape with a larger diameter end of the frustoconical shape facing toward the insert receptacle opening of the shell.

12. The implant of claim 3 wherein:

(a) the insert member has an outer transverse cross-sectional size and shape that remains substantially constant as the insert member is inserted into the insert receptacle of the shell.

* * * * *

US005176680A

United States Patent [19]

Vignaud et al.

[11] Patent Number: 5,176,680

[45] Date of Patent: Jan. 5, 1993

[54] DEVICE FOR THE ADJUSTABLE FIXING OF SPINAL OSTEOSYNTHESIS RODS

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[21] Appl. No.: **652,101**

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Mar. 19, 1990 [FR] France 90 03694

[51] Int. Cl.[5] **A61F 2/00**
[52] U.S. Cl. **606/61**; 606/60; 606/73
[58] Field of Search 606/54-62, 606/64, 72, 73

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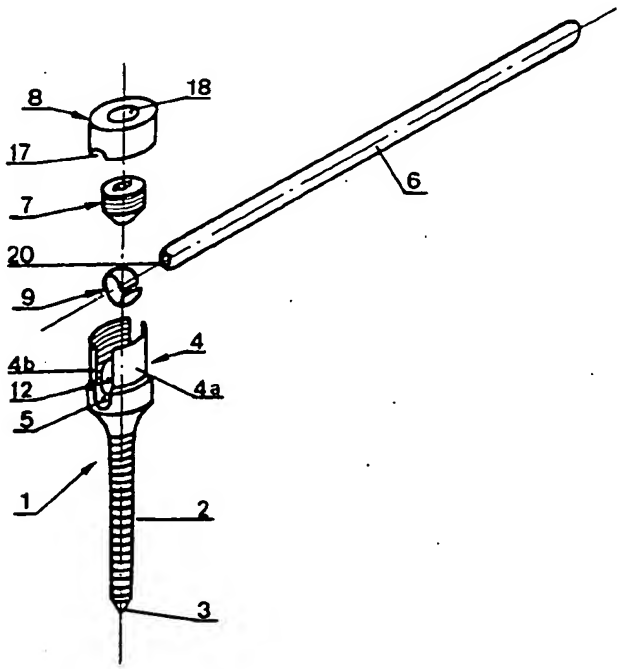
Primary Examiner—Richard J. Apley
Assistant Examiner—Linda C. M. Dvorak
Attorney, Agent, or Firm—Roylance, Abrams, Berdo & Goodman

[57] **ABSTRACT**

The present invention concerns a device for fixing osteosynthesis rods to pedicular screws (1), the device being of the type including a diapason-shaped head (4) defining two branches (4*a*, 4*b*) collectively receiving a rod (6) to be fixed, the head being locked in its housing (5) by a locking screw (7), wherein it further includes, threaded on the rod (6) and inserted between the locking screw (7) and the bottom of the housing (5), a split ring (9) whose opposing external faces (10) directed towards the locking screw (7) and said bottom are convex and received in complementary concave surfaces (11, 12) provided on the extremity of the locking screw (7) and the bottom of the receiving housing (5) of the rod (6), the ring (9), prior to locking of the screw (7), allowing for a certain angular clearance of the rod (6) with respect to the axis of the screw (1).

16 Claims, 2 Drawing Sheets



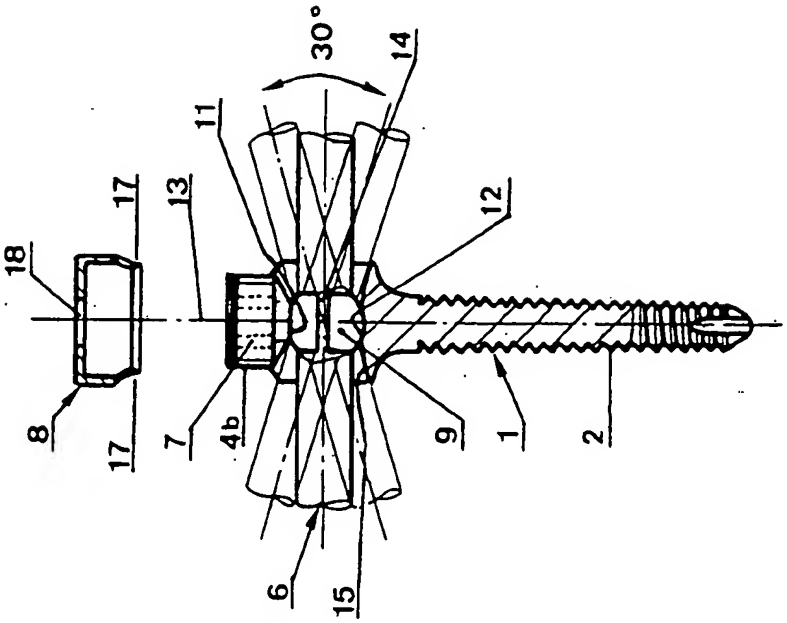


FIG 2

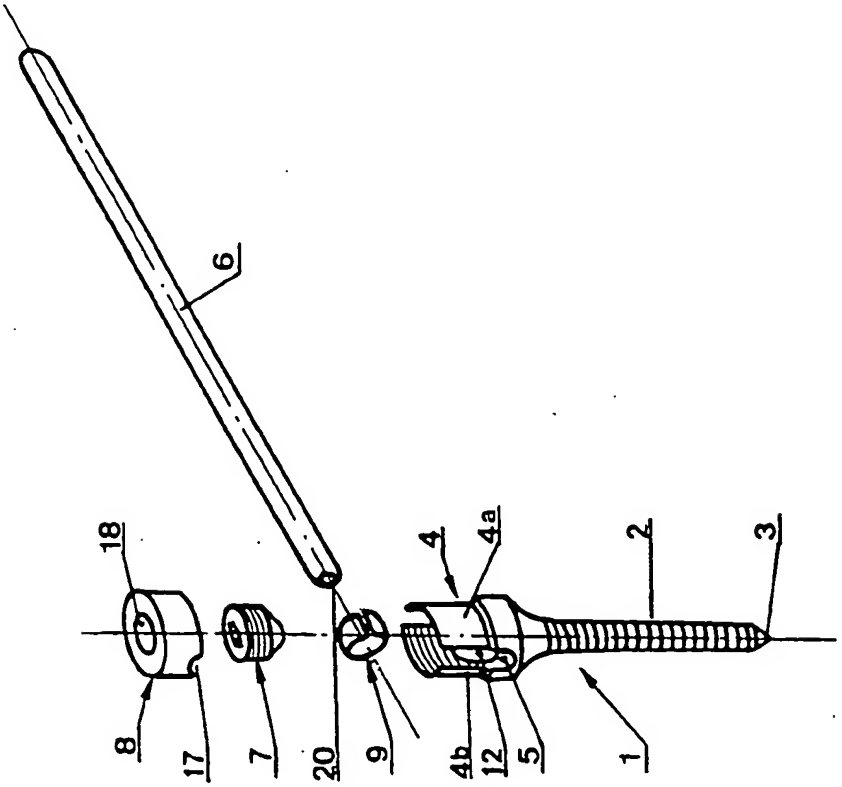


FIG 1

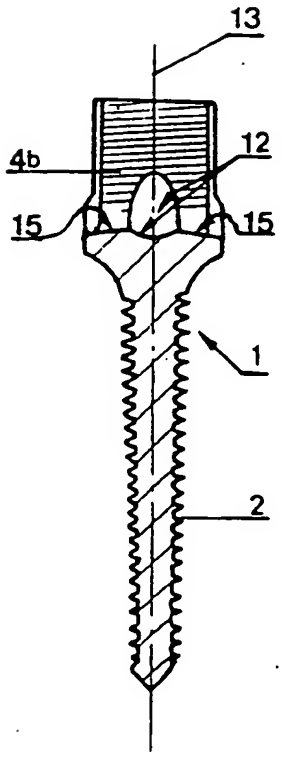


FIG 3

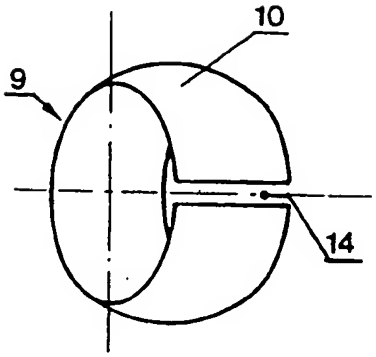


FIG 4

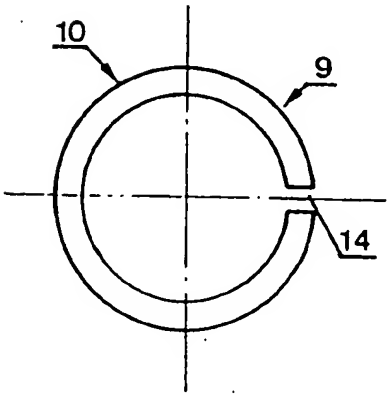


FIG 5

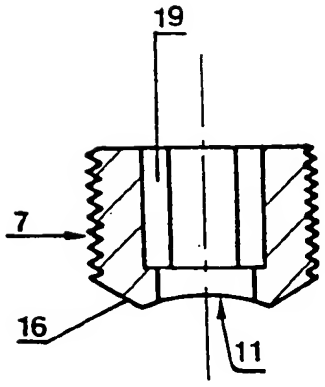


FIG 6

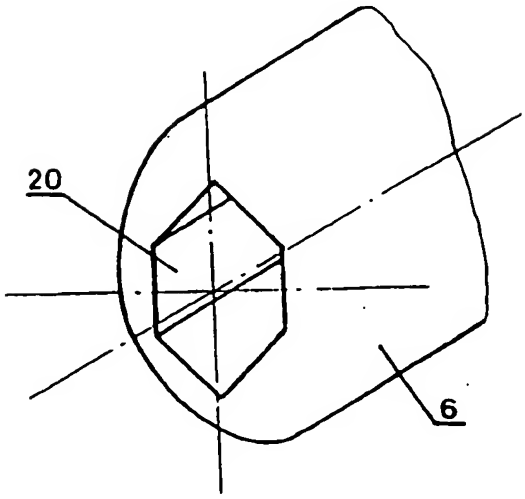


FIG 7

DEVICE FOR THE ADJUSTABLE FIXING OF SPINAL OSTEOSYNTHESIS RODS

FIELD OF THE INVENTION

The present invention concerns an adjustable spinal instrument for pedicle fixing and makes it possible to adapt and re-establish the physiological curves of the spine.

BACKGROUND OF THE INVENTION

Generally speaking, joined pedicle screws are implanted by rods or plates, the screw in all cases being strictly perpendicular to the rod or plate.

SUMMARY OF THE INVENTION

The invention seeks to overcome this drawback and offers a rod fixing device enabling the rods to be adjusted with respect to the axis of the pedicle screws.

To this effect, the object of the invention is to provide a device for fixing spinal osteosynthesis rods on pedicle screws of the type including a diapason-shaped head defining two branches receiving a rod to be fixed, said rod being locked in its housing by a locking screw, wherein it further comprises, fitted onto the rod and inserted between the locking screw and the bottom of said housing, a split ring whose external opposing faces directed towards said locking screw and said bottom are convex and received in complementary concave surfaces provided on the extremity of the locking screw and the bottom of the receiving housing of the rod, said ring authorizing a certain angular clearance of the rod with respect to the axis of the screw prior to locking of the screw.

Such a device makes it possible to adjust the angle formed by the rod with the axis of the pedicle screw, especially in the sagittal plane, and to lock the rod in the desired position by virtue of the split ring which deforms and immobilizes the rod under the pressure of the locking screw.

BRIEF DESCRIPTION OF THE DRAWINGS

Other characteristics and advantages of the invention shall appear more readily from a reading of the following description of an embodiment of the device of the invention, this description being given solely by way of example and with reference to the accompanying drawings on which:

FIG. 1 is an exploded view of a device conforming to the invention;

FIG. 2 shows the device of FIG. 1, the device being assembled except for the cap;

FIG. 3 is a section along the sagittal plane of a pedicle screw according to the invention;

FIG. 4 is a perspective view of a split ring according to the invention;

FIG. 5 is a lateral front view of the ring of FIG. 4;

FIG. 6 is an axial cutaway view of a locking screw according to the invention, and

FIG. 7 is an enlarged view of the extremity of the rod of FIG. 1.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows at 1 a known type of pedicle screw. It comprises a conical screw 2, an ogival point 3 and a diapason-shaped cylindrical head 4 pierced on both sides. More specifically, the head 4 comprises two opposing parallel branches 4*a* and 4*b* collectively defining a scalloping or housing 5 with a general axis perpendicular to the axis of the screw 2 and able to receive a generally cylindrically shaped rod or integralization element 6. Such a structure is well known and is described in the document GB-2.173.104, for example.

The opposing internal faces of the branches 4*a* and 4*b* are cylindrical and threaded in such a way as to receive a locking screw 7 for locking the rod 6 in its housing 5 in the same way as the screw locking device described in the document EP-0.010.527.

The head 4 receives a cap 8 covering the upper extremities of the branches 4*a* and 4*b*.

In accordance with the invention, locking of the rod 6 is ensured by means of a split ring 9 able to slide freely over the rod 6 received in the housing 5 and locked by the locking screw 7.

The ring 9, the extremity of the locking screw 7 and the portion of the housing 5 in contact with the ring 9 are made to conform with one another in a particular way.

In the embodiment represented, the ring 9 comprises (FIG. 4) an external spherical convex surface 10 cooperating firstly with a spherical concave surface 11 (FIG. 6) provided at the extremity of the conical section of the locking screw 7, and secondly with a spherical concave surface 12 (FIG. 3) provided in the bottom of the housing 5 to receive the rod 6 between branches 4*a* and 4*b* of head 4.

The ring 9 is disposed in such a way that its plane is approximately perpendicular (FIG. 2) to the sagittal plane of the screw 1, which is defined by the axis 13 of the screw and the general axis of the housing 5 receiving the rod 6.

The ring 9 is provided with a straight slot 14 (FIGS. 4 and 5) and has one internal cylindrical face 15 just slightly larger than the diameter of the rod 6.

The rod 6 on which a ring 9 is fitted is inserted inside the housing 5 of the pedicular screw 1 after placing this screw in the appropriate bony portion. The ring 9 is engaged in the housing 5, 12 as shown on FIG. 2, then the locking screw 7 is screwed into the space between the branches 4*a* and 4*b*. Before locking the ring 9, the cap 8 is placed by simply being engaged astride the two branches 4*a* and 4*b*, then the rod 6 is suitably orientated inside the sagittal plane (FIG. 2) and locked with the desired orientation by compressing the split ring 9 with the locking screw 7. The angular clearance of the rod 6 is, for example, 15° around the position perpendicular to the axis 13 of the screw 1, as illustrated by FIG. 2.

When adjusting the rod 6, the ring 9 slides over the spherical surfaces 11 and 12 confining the rod.

So as to allow for the free angular clearance of the rod 6, the bottom of the housing 5 at the right of two opposing inlets is slightly recessed at 15 (FIGS. 2 and 3), the truncated section 16 of the point of the locking screw 7 (FIG. 6) ensuring the free clearance of the rod from the locking screw side.

The cap 8 comprises (FIG. 2) two opposing scallopings 17 for the free clearance of the rod 6 and a central piercing 18 for the passage of a wrench, such as a six-sided wrench, for tightening the locking screw 7 by means of a hollow six-sided recession 19 provided in the upper face of said screw 7.

The role of the cap is mainly to avoid spacing of the two branches 4*a* and 4*b* when tightening the locking screw. The cap 8 may be suppressed if the material of

the screw 1 or the size of the branches 4*a*, 4*b*, especially relative to its thickness, so allows.

A thorough tightening of the locking screw 7 causes the rod 6 to be locked by the ring 9 in the selected position, the aperture 14 preferably being placed laterally, as shown on FIG. 2.

The rod is thus completely locked, both as regards its orientation and rotation around its axis.

The rod 6 may, for example, be a smooth interlocking element provided at its two extremities with a hollow six-sided recession (FIG. 7) or even an element made up of flexible plaited cylindrical strands.

By providing holes or recessions 20, this allows a complementary shaped wrench to be introduced with a view to acting on the derotation of the vertebral column.

In effect, by acting with wrenches on the rotation in the same direction of the rod 6 on its axis, this rod is made to rotate and accordingly the spline rotates along its vertical axis.

Finally, the invention is clearly not merely restricted to the embodiment described above, but covers all possible variants, especially as regards the shape and disposition of the convex and concave surfaces respectively of the ring 9 and the surfaces 11 and 12 between which it is screwed and as regards the locking screw 7 which may be screwed in the opposing branches 4*a* and 4*b* or in a piece mounted on the head 4 of the screw. Similarly, the shapes and dimensions of the ring 9 and the slot 14 may also vary without departing from the context of the invention to the extent that the slot plays the same role for elastic clamping the ring by crushing it on the rod to be locked.

In addition, the extremities of the rod 6 may generally have an internal or external angular shape, as shown on FIG. 7, the contour of this shape able to be any, such as polygonal with n sides, and suitably-adapted to the contour of the wrench allowing the rod 6 to be rotated on its axis.

What is claimed is:

1. A device for fixing a spinal osteosynthesis rod, comprising:

a pedicle screw having a diapason-shaped head with two spaced branches defining a housing for receiving a rod to be fixed therein, said housing having a bottom surface with a concave surface;

a locking screw, coupled to said head, for blocking the rod in said housing, said locking screw having an end with a concave surface; and

a split ring configured to be fitted onto the rod and inserted between said locking screw and said bottom surface of said housing, said ring having opposing external convex faces directed toward said locking screw and said bottom surface, respectively, said convex faces engaging and being complimentary to said concave surfaces of said bottom surface and said locking screw;

whereby, said ring allows predetermined angular clearance of the rod relative to said pedicle screw prior to tightening of said locking screw.

2. A device according to claim 1 wherein said concave surfaces and convex faces are spherical.

3. A device according to claim 2 wherein said locking screw comprises a central truncated conical point defining said concave surface thereon.

4. A device according to claim 3 wherein said bottom surface of said housing has clearance recesses on opposite sides of said concave surface of said bottom surface in inlet areas of said housing, providing angular clearance for the rod.

5. A device according to claim 3 wherein a cap covers said branches of said pedicle screw and said locking screw, said cap having a central hole providing access to an operating recess in said locking screw.

6. A device according to claim 2 wherein said bottom surface of said housing has clearance recesses on opposite sides of said concave surface of said bottom surface in inlet areas of said housing, providing angular clearance for the rod.

7. A device according to claim 2 wherein a cap covers said branches of said pedicle screw and said locking screw, said cap having a central hole providing access to an operating recess in said locking screw.

8. A device according to claim 1 wherein said locking screw comprises a central truncated conical point defining said concave surface thereon.

9. A device according to claim 8 wherein said bottom surface of said housing has clearance recesses on opposite sides of said concave surface of said bottom surface in inlet areas of said housing, providing angular clearance for the rod.

10. A device according to claim 9 wherein a cap covers said branches of said pedicle screw and said locking screw, said cap having a central hole providing access to an operating recess in said locking screw.

11. A device according to claim 10 wherein said cap comprises opposing scallops on an edge thereof providing angular clearance for the rod.

12. A device according to claim 1 wherein said bottom surface of said housing has clearance recesses on opposite sides of said concave surface of said bottom surface in inlet areas of said housing, providing angular clearance for the rod.

13. A device according to claim 12 wherein a cap covers said branches of said pedicle screw and said locking screw, said cap having a central hole providing access to an operating recess in said locking screw.

14. A device according to claim 1 wherein a cap covers said branches of said pedicle screw and said locking screw, said cap having a central hole providing access to an operating recess in said locking screw.

15. A device according to claim 14 wherein said cap comprises opposing scallops on an edge thereof providing angular clearance for the rod.

16. A device according to claim 1 further comprising the rod fitted into said split ring, said rod having a recess for receiving a wrench to rotate said rod about a longitudinal axis.

* * * * *

United States Patent [19]

Sugiyama et al.

[11] **4,435,101**

[45] **Mar. 6, 1984**

[54] **BALL JOINT**

[75] Inventors: **Minoru Sugiyama; Shinji Kaneko, both of Kanagawa, Japan**

[73] Assignee: **Tokico Ltd., Kawasaki, Japan**

[21] Appl. No.: **333,615**

[22] Filed: **Dec. 22, 1981**

[30] **Foreign Application Priority Data**

Dec. 29, 1980 [JP] Japan ..... 55-191263[U]

[51] **Int. Cl.**³ **F16C 11/06**

[52] **U.S. Cl.** **403/122**; 156/73.1; 156/304.2; 403/141; 403/144

[58] **Field of Search** ..... 156/70, 73.1, 304.2, 156/580.1, 580.2; 403/122, 141, 142, 143, 132, 144, 135; 228/110, 1 R

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Primary Examiner—Michael G. Wityshyn
Attorney, Agent, or Firm—Wenderoth, Lind & Ponack

[57] **ABSTRACT**

A ball joint including a ball member having a ball end, a socket member having a recess for pivotally receiving the ball end of the ball member and a retaining ring received in the recess of the socket member for retaining the ball end of the ball member in the recess. The socket member consists of at least two components of synthetic resin material, and the components are welded together by supersonic welding process.

5 Claims, 10 Drawing Figures

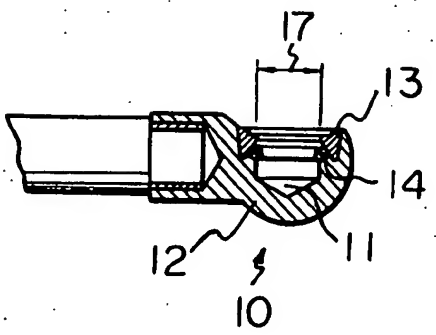


Fig. 1

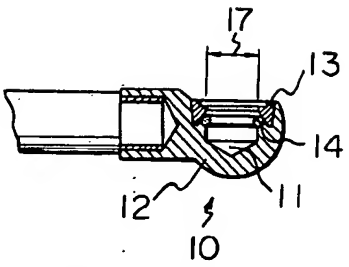


Fig. 2

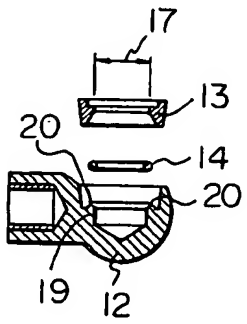


Fig. 3

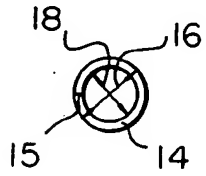


Fig. 4

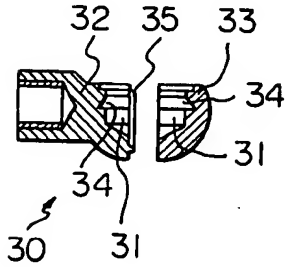


Fig. 5

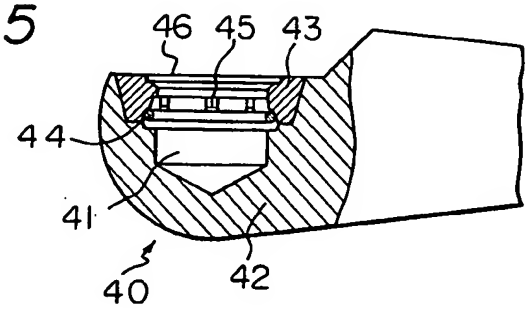


Fig. 6

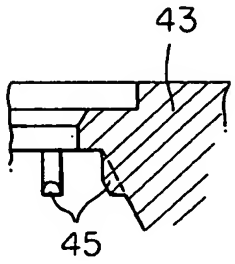


Fig. 7
PRIOR ART

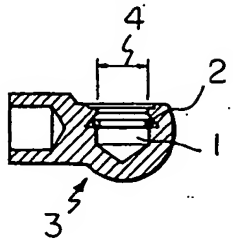


Fig. 8
PRIOR ART

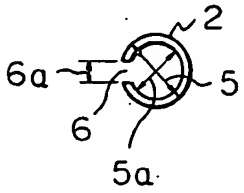


Fig. 9
PRIOR ART

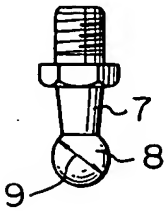
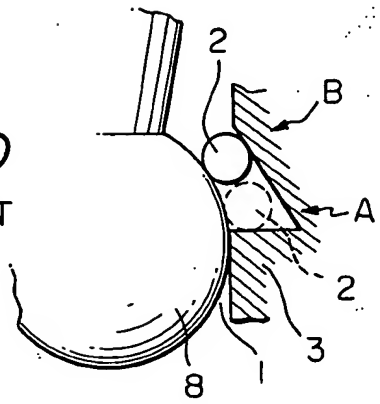


Fig. 10
PRIOR ART



BALL JOINT

BACKGROUND OF THE INVENTION

This invention relates to a ball joint including a ball member having a ball end and a socket member having a recess for pivotally receiving the ball end of the ball member.

Usually, the diameter of the opening of the recess is larger than that of the ball end of the ball member, and an annular retaining ring is fitted in the recess for preventing the ball end from escaping out. In its normal uncompressed condition, the outer diameter of the retaining ring is larger than the diameter of the opening of the recess and the inner diameter of the retaining ring is smaller than the diameter of the ball end so that the ball end is effectively retained in the recess. However, there has been provided a substantial amount of circumferential gap in the retaining ring so as to permit the retaining ring to be compressed with the diameter thereof being reduced in inserting the retaining ring into the recess. However, when the ball member is strongly pulled in the direction of escape from the recess, the retaining ring may sometimes be compressed in the direction which reduces the gap thereby reducing the diameter and allowing the ball member to escape from the recess. Thus, the prior art ball joint has a shortcoming that the connection between the ball member and the socket member is not reliable.

SUMMARY OF THE INVENTION

The present invention aims to solve the shortcoming aforementioned. According to the invention, the socket member of the ball joint consists of at least two components which are formed respectively of synthetic resin material and are welded together by a supersonic welding process. The supersonic welding process is performed with the ball member and the retaining ring assembled in the recess of the socket member. Preferably, the retaining ring does not have any substantial circumferential gap in the assembled condition.

One of the two components of the socket member may have an annular configuration with the inner diameter thereof defining the opening of the recess of the assembled socket member. Alternatively, the two components of the socket member may be welded together along a plane including the longitudinal or transverse central plane of the recess.

BRIEF DESCRIPTION OF THE DRAWINGS

Further objects and advantages of the invention will hereinafter be described with reference to the drawings, wherein:

FIG. 1 is a longitudinal sectional view of a socket member of a ball joint according to the invention with a retaining ring being fitted therein;

FIG. 2 is a cross-sectional exploded view of the socket member and retaining ring of FIG. 1;

FIG. 3 is a plan view of the retaining ring of FIG. 1;

FIG. 4 is a cross-sectional exploded view of a socket member according to a second embodiment of the invention;

FIG. 5 is a longitudinal sectional view of a socket member according to a third embodiment of the invention;

FIG. 6 is an enlarged partial sectional view of the socket member of FIG. 5;

FIG. 7 is a sectional view showing a prior art socket member;

FIG. 8 is a plan view of a retaining ring incorporated in the socket member of FIG. 7;

FIG. 9 is a side view of a ball member; and

FIG. 10 is a schematic partial sectional view showing the movement of the ball member and the retaining ring relative to the socket member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. 7–8 show a typical prior art ball joint consisting of a socket member 3 having a recess 1 therein, a ball member 7 having a ball end 8 (FIG. 9) and an annular retaining ring 2 having a circumferential gap 6*a*. The ring 2 is fitted in the recess 1, however, since the diameter 4 of the opening of the recess 1 is smaller than the outer diameter 5 of the retaining 2, it has been required to compress the retaining ring 1 in inserting the ring 2 into the recess 1. The circumferential gap 6*a* of the ring 2 permits the ring 2 to be compressed. The inner diameter 5*a* of the ring 2 is, in the normal condition, smaller than the diameter 9 of the ball end of the ball member. In assembling the ball joint, the ring 2 is firstly fitted in the recess 1, and the ring 2 is expanded, in assembling the ball member with the socket member, so that the inner diameter 5*a* of the retaining ring expands to permit the ball end of the ball member to pass through the retaining ring.

When the ball end 8 tends to escape from the recess 1, the ring 2 moves from position A to position B as seen in FIG. 10 and engages with the wall of the recess 1 and the ball end 8 and, in the normal condition, the ring 2 maintains the circumferential gap 6*a* with the inner diameter 5*a* being smaller than the diameter 9 of the ball end 8 and the outer diameter 5 being larger than the diameter 4 of the opening in the recess 1, thus effectively retains the ball end 8 in the recess 1. However, there is a tendency that, according to the inclined surface in the recess 1, when the ball end 8 is strongly pulled, the ring 2 is compressed in the direction reducing the circumferential gap, and as the result, the outer diameter of the ring 2 decreases and the ball end 8 and the ring 2 escape from of the recess 1.

A preferred embodiment of the invention is shown in FIGS. 1–3. A socket member 10 shown in FIGS. 1 and 2 consists of a first or a main component 12 having a recess 14 and a second annular component 13 welded to the main component 12 by means of a supersonic welding process. The components 12 and 13 are formed of synthetic resin material such as glass fiber reinforced nylon or a mixture of polycarbonate and glass fiber. The ring 14 has a circumferential gap 15 the amount of which is substantially zero in the normal, unexpanded condition. The outer diameter 16 of the ring 14 is larger than the inner diameter 17 of the annular component 13 and the inner diameter 18 of the ring 14 is smaller than the diameter of a ball end of a ball member cooperating with the socket member 10. The ball member may be similar to the ball member 7 shown in FIG. 9. In assembling the ball member with the socket member 10 with the ring 14 being assembled as shown in FIG. 1, the ring 14 is expanded so as to pass the ball end of the ball member therethrough with the circumferential gap 15 being increased. When the ball end of the ball member has passed through the ring 14, the ring 14 contracts due to its resiliency.

According to the invention, the components 12 and 13 of the socket member 10 are then welded together by supersonic welding process. To aid the welding process, there is provided an annular projection 20 on an annular shoulder 19 of the first component 12 as shown in FIG. 2. The projection 20 firstly melts in the supersonic welding process and flows along the mating surfaces between the components 12 and 13. The two components are reliably and firmly welded together.

In the embodiment of FIGS. 1 and 2, the second component 13 of the socket member 10 constitutes a retaining portion defining the opening 17 of the recess 11. However, in the embodiment of FIG. 4, two components 32 and 33 of the socket member 30 are mated along a plane transverse the longitudinal axis of the socket member and passing through the center of the recess 31 which receives the ball end of the ball member. Similarly to the embodiment of FIG. 2, there is provided a semi-circular projection 35 on the mating surface of either of the components 32 and 33 so as to obtain a reliable welding between the components 32 and 33. FIG. 4 does not show any retaining ring, but it will be understood that a retaining ring similar to the retaining ring 14 is located in the annular portion depicted by the reference numeral 34 prior to the supersonic welding process. The diameter of the annular portion 34 permits the expansion of the retaining ring in inserting the ball end of a ball member into the recess 31 of the socket member 30.

FIGS. 5 and 6 show another embodiment of the invention. The socket member 40 shown in FIG. 5 consists, similar to the embodiment of FIGS. 1 and 2, of a first component 42 and an annular second component 43. The component 43 has a plurality of circumferentially spaced projections 45 on the inner circumference which engage with a retaining ring 44 to prevent the retaining ring from escaping out. Further, the space between the projections 45 can serve as a reservoir of lubricant such as grease.

In the embodiments, the recesses 1, 11, 31 and 41 are shown to have a generally cylindrical shape provided with a cone-like bottom, but the recess may have a spherical or part spherical form.

As described heretofore, according to the invention, the socket member of the ball joint is formed of at least two components which are formed of synthetic resin material and are welded together by a supersonic welding process. Thus, it is possible to utilize a retaining ring having a substantially zero gap, whereby the escape of the ball member can reliably be prevented. Since the socket member is formed of synthetic resin material, the fabrication process is easy and the costs can be reduced.

What is claimed is:

1. A ball joint including:

a ball member having a ball end;

a socket member comprising two components formed of synthetic resin material, having a recess therein for receiving said ball end of said ball member, said recess having a ring receiving portion at the upper end thereof; and

an annular metal retaining ring having a split therein of normally zero gap received in said ring receiving portion of said recess, said ring being resiliently radially expandable, said gap widening during expansion of said ring, said ring in its unexpanded state having an inner diameter less than the diameter of said ball end;

said two components being supersonically welded together so as to irremovably hold said ring in said ring receiving portion, said ring receiving portion being shaped to permit said ring to radially expand to receive said ball end therethrough into said recess when said ball end is pushed downward thereon, and to block said ring from expanding when said ball end is pulled outward against said ring from within said recess, so as to block removal of said ball end from said recess.

2. A ball joint according to claim 1 wherein the socket member consists of a primary component having said recess for receiving the ball end of the ball member, and an annular retaining component supersonically welded on the primary component above said ring so as to block upward movement of said ring.

3. A ball joint according to claim 1 wherein the socket member consists of two components which are welded together along a plane which is perpendicular to the plane of the retaining ring and includes the center of the ball end of the ball member.

4. A ball joint as in claim 1, wherein said socket member has a circular opening whose diameter is at least as large as the diameter of said ball end and less than the outer diameter of said ring in its unexpanded state.

5. A ball joint as in claim 1, wherein said two components are welded along a weld line defining a substantially closed path of said dimensions that said ring member can be passed therethrough so that said ring can be inserted in said ring receiving portion before said two components are supersonically welded.

* * * * *

United States Patent [19]

Khovaylo

[11] **4,241,463**

[45] **Dec. 30, 1980**

[54] **PROSTHETIC IMPLANT DEVICE**

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[73] Assignee: **Precision Cast Specialties, Inc., Emerson, N.J.**

[21] Appl. No.: **951,883**

[22] Filed: **Oct. 16, 1978**

[51] Int. Cl.³ **A61F 1/03**

[52] U.S. Cl. ..... **3/1.913**; 128/92 CA; 403/135; 403/143

[58] Field of Search ..... 3/1.9, 1.91, 1.911, 3/1.912, 1.913; 128/92 CA; 403/143, 135, 140, 122, 326

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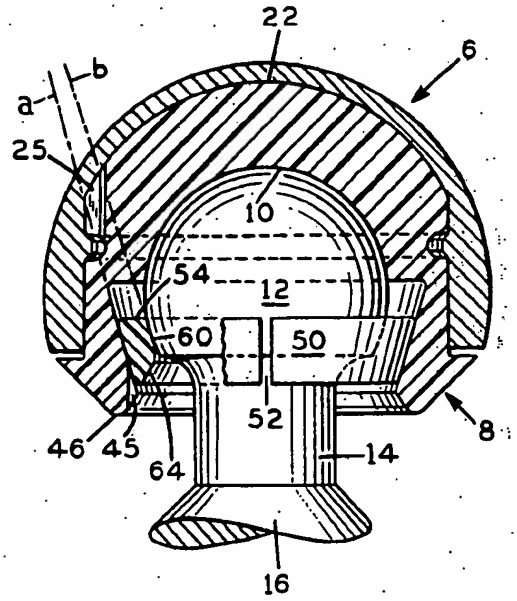
Primary Examiner—Clifford D. Crowder

[57] **ABSTRACT**

A prosthetic joint for use in replacing the ball end of a biological joint, the replacement including a spherical head for insertion into a natural socket, an insert in the head and locked therein by an inwardly projecting ring in the head and a groove in the insert, a ball shaped member seated in the insert and having a neck and a stem for mounting the joint on the end of the biological member on which the ball is being replaced and a ring having a downwardly and inwardly sloping outer wall seating in a recess in the plastic insert and locking the ball shaped member in the insert.

15 Claims, 5 Drawing Figures



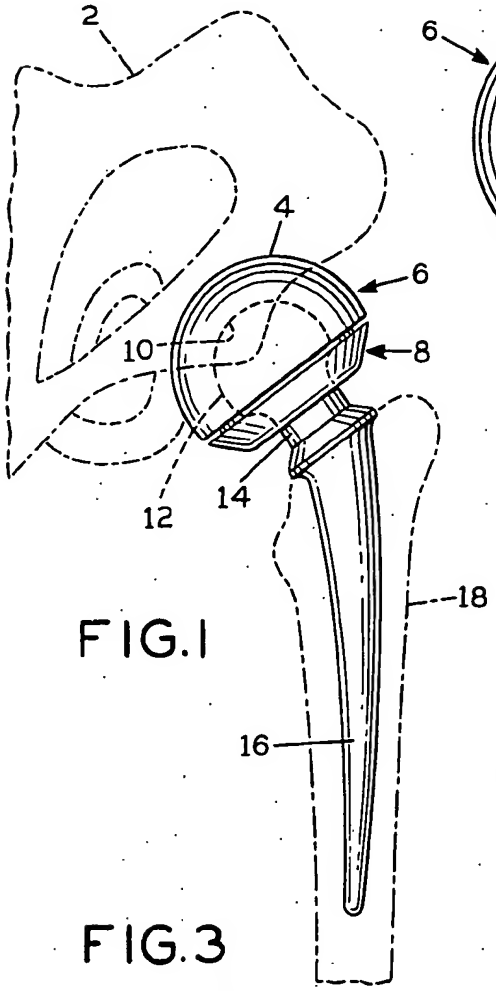


FIG. 1

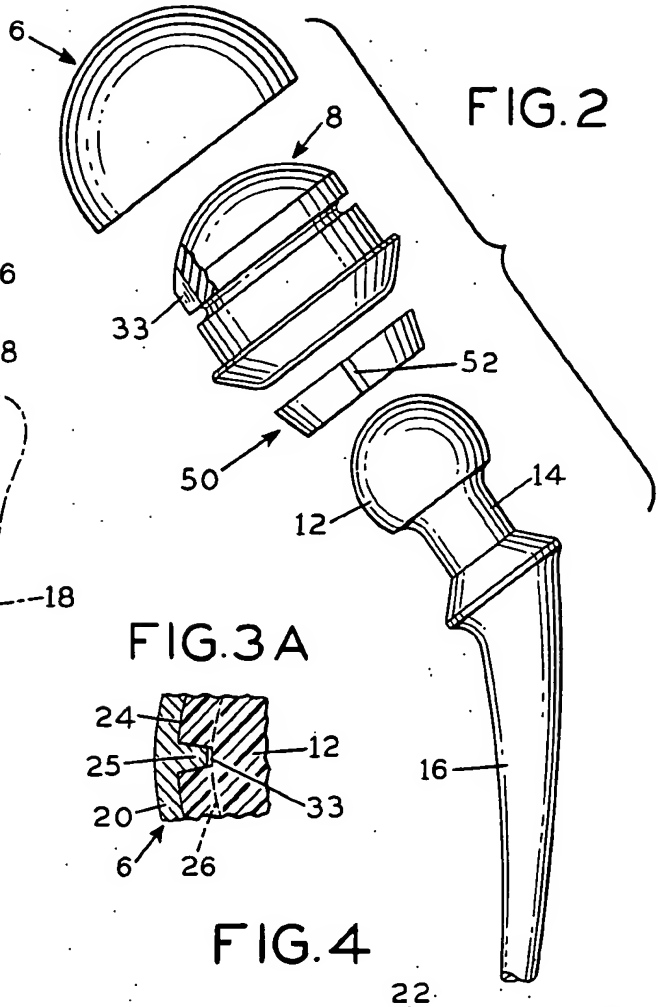


FIG. 2

FIG. 3A

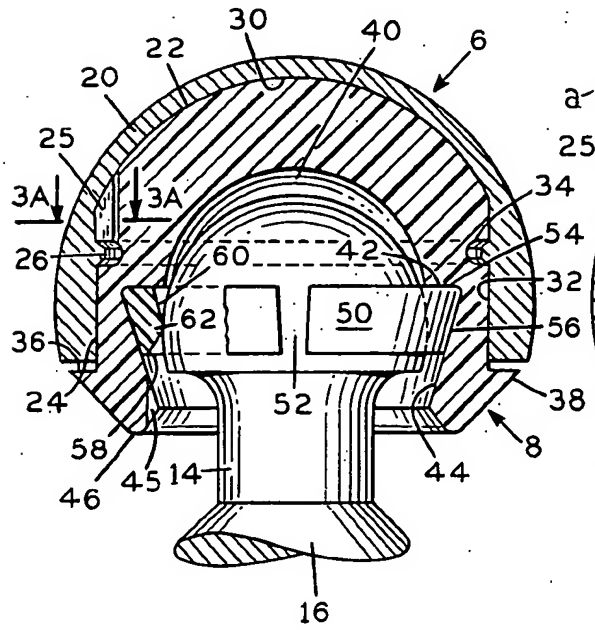


FIG. 3

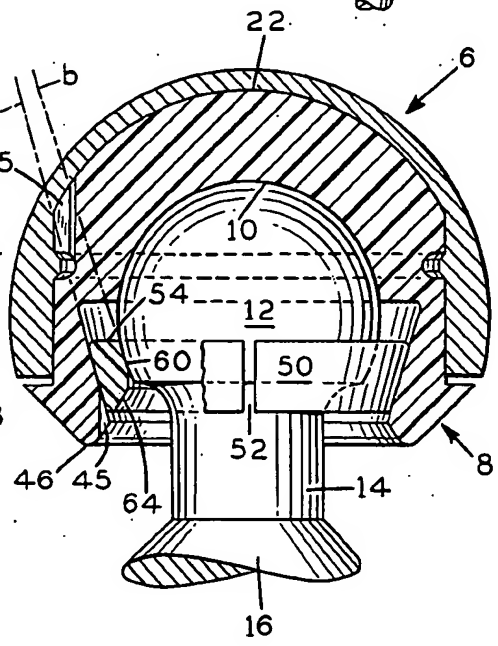


FIG. 4

PROSTHETIC IMPLANT DEVICE

This invention relates to fem ral hip prosthesis, and, more particularly, to a femoral head and neck prosthesis for implant and interaction with the natural bone structure of the pelvic acetabulum.

The pelvis in the human body contains two hip bones, one on each side of the body and each containing an acetabulum or hip socket for receiving and forming a seat for the femoral head, or ball, of the femur or thigh bone. The femoral head is connected to the thigh bone by a neck which is angularly disposed relative to the axis of the femur and relative to the vertical axis of the body. Thus, any load applied by the body through the hip and femur neck to the thigh bone and leg and any impacts, such as in walking, jumping and the like, applied by the leg and thigh bone through the femur neck and hip to the body are transmitted angularly through the femur neck. This angular transmitting of the load and forces through the femur neck results in high stresses and high sheer loads applied to the femur neck. These high stresses, abnormally applied, can cause dislocation of the femoral head from the acetabulum or hip socket and fracture and breaking of the femur neck. In older people, such femur neck often becomes brittle and, in both older and younger people is subject to injury. Replacement is often required.

In some instances, both the acetabulum or hip socket and the femoral head or ball and neck require replacement. In other instances, where injury or damage is limited to the femoral head and femur neck, only the head and neck require replacement. The replacement of the femoral head and neck without the replacement of the acetabulum is, of course, a much easier surgical procedure and desirable.

Various attempts have, heretofore, been made to provide femoral head and necks for surgical implant in the natural acetabulum and replacement of the natural head and neck damaged or broken. Thus, in U.S. Pat. Nos. 3,813,699 and 3,863,273 there are shown and described femoral heads and necks for such surgical implant and replacement for damaged or broken natural heads or necks. In both such devices, an outer spherical metal cup, having an inner plastic insert, is provided for implanting in the acetabulum or hip socket. The inner plastic insert has a socket into which a metal sphere, having a neck and a stem for connection to the thigh bone, is pivotally received.

While the devices of such patents provide replacements for surgical implant when the natural femoral head or neck are broken or damaged, such devices can become displaced after implant. Thus, the outer spherical metal cup may become displaced from the hip socket, the inner plastic insert may become displaced from the outer cup or the metal sphere may become displaced from the plastic insert. Such displacement may arise when the leg or body is abnormally twisted much in the same manner as might result in dislocation in the normal hip in a person having a propensity for hip dislocation. The difficulty in such patented devices when dislocation occurs is in the relocation of the implant once dislocation occurs without resort to new surgery. While the parts dislocated might be identified in the customary manner, such as by x-ray, such devices do not readily lend themselves to relocation without surgery. This is because, in attempting to realign or relocate the dislocated elements with each other, such as by twisting or pulling in the conventional manner, other parts in the device, at the time aligned and properly located, can be misaligned and dislocated, compounding rather than correcting the original dislocation. Such compounding can require surgical correction. Furthermore, in attempting to relocate and realign the devices of the patents, damage to the natural bone and body tissues in the vicinity of the joint may also result.

In the instant invention, many of the difficulties heretofore encountered in providing an implantable replacement for the femoral head and neck for use with the natural acetabulum or hip joint are overcome. While still employing an outer spherical cup, an inner insert and a metal sphere having a neck and a stem for connection to the thigh bone, the cup, insert and sphere are interconnected and implanted in the natural acetabulum in such a manner that dislocation or misalignment of the component parts, one to the other, is avoided. Furthermore, the various components are shaped and assembled so as to avoid contact between the hard edges with bone and body tissue should dislocation of the assembly and the natural acetabulum or hip socket arise and relocation and realignment, such as through twisting and pulling, become necessary.

The femoral head and neck prosthetic implant of the instant invention includes an outer spherical cup, an inner insert and a metal sphere having a neck and a stem for connection to the thigh bone and for insertion into a socket in the inner insert. The outer cup may be of metal and the inner insert may be of plastic and the cup and insert may be interconnected by a mating protruberance and groove and the plastic insert extends outwardly and along the edge of the metal cup for purposes more fully described later herein. The outer cup and the inner insert may be of one piece such as of impact and abrasive resistant ceramic having a low coefficient of friction. The lower or entry end of the inner insert socket is tapered and slopes downwardly and inwardly toward the socket open end. A plastic split ring, having a sloping outer wall corresponding with the slope on the wall of the insert and a curved inner wall for seating on the spherical surface of the metal sphere are provided between the metal sphere and the insert so that the metal sphere might be inserted into the insert and, once in place, will be locked for pivotal movement in the insert.

The invention of the instant application will be more fully discussed and better understood from the following description, taken with the appended drawings, in which

FIG. 1 is a view, in full and phantom lines and taken from the front, showing in phantom line, the natural pelvis, acetabulum, and thigh bone and, in full line, the implant device of the instant invention;

FIG. 2 is an enlarged exploded view, of the implant device of the instant invention showing the parts in their relative assembly position;

FIG. 3 is an enlarged view, partly in section, showing the outer spherical cup, the inner plastic insert, the metal sphere and neck, as the metal sphere is being inserted into the outer spherical cup and plastic insert assembly;

FIG. 3A is a sectional view taken at 3A—3A FIG. 3; and

FIG. 4 is an enlarged view, similar to FIG. 3 but showing the metal sphere, outer cup and plastic insert assembled.

Referring to the drawings, the pelvis, generally designated 2, has an acetabulum or hip socket 4. The spherical cup, generally designated 6, has an insert, generally designated 8, seated in sphere 6 and in turn having a socket 10 for receiving sphere 12, having a neck 14 and stem 16 for implant in thigh bone 18.

The materials of spherical cup 6, insert 8, sphere 12, neck 14 and stem 16 may be of any material compatible with bone and body tissues of the patient in which the implant device of the instant invention is to be implanted and of sufficient strength to withstand forces which will be encountered. Cup 6 and insert 8 may be of one piece and of impact, wear and abrasive resistant ceramic and neck 14 and stem 16 might be of metal. Preferably, spherical cup 6, sphere 12, neck 14 and stem 16 are of a metal material. Materials such as cobalt chrome molybdenum alloy ASTM F-75 and stainless steel ASTM F-139-71 are especially suited for this purpose. Insert 8 is preferably made from a low-friction material having sufficient strength, abrasive resistance and rigidity to accomodate the forces which will be applied. Ultra-high molecular weight polyethylene is a material suitable for this purpose.

Referring, now, to FIGS. 3 and 4, spherical cup 6 has an outer spherical surface 20 and an inner spherical dome 22. Spherical dome 22 terminates in a cylindrical skirt 24, extending downwardly from the dome to the open end of the spherical cup 6. Just below the point where dome 22 joins cylindrical skirt 24, skirt 24 is provided with a key 25 and an inwardly extending protruberance or ring 26 extending circumferentially around skirt 24. The outer surface of plastic insert 8 is shaped to the configuration of the inner surface of spherical cup 6. Thus, insert 8 has an outer spherical dome 30, and downwardly and cylindrically extending skirt 32, keyway 33 and recess 34 into which the key and protruberance on spherical cup 6 extend when plastic insert 8 is inserted in spherical cup 6 as shown in FIGS. 3 and 4. At its lower end, below skirt 32, the outer wall of plastic insert 8 extends outwardly at 36, along the bottom wall of spherical cup 6 and then slopes downwardly and inwardly, at 38 to the open end of insert 8.

The inner surface of plastic insert 8 is domed at 40 to receive spherical head 12. Below dome 40, the inner wall on insert 8 extends outwardly at 42 and then slopes downwardly and inwardly at 44 where it joins the outer wall rounded at 46. At its lower end, wall 44 is provided with a slot 45. For reasons which will be more apparent later herein, the slope of wall 44 and slot 45 are of substantial importance.

A ring, generally designated 50, preferably of the same plastic material as the plastic material of the insert and having a split at 52, has a top wall 54, a downwardly and inwardly sloping outer wall 56 of the same slope as wall 44 of insert 8 and for mating engagement therewith, a bottom wall 58 and an inner wall curved at 60 to mate with the wall of spherical head 12 when insert 50 is in the downward locked position, in FIG. 4, an intermediate portion 62 to mate with the spherical surface of sphere 12 as the sphere is being inserted into insert 8, through ring 50, FIG. 3 and a tapered bottom wall 64 joining curved inner wall portion 62 with bottom wall 58.

The slope of inner wall 44 of insert 8 and the slope of outer ring wall 56 and of ring 50, taken with the slope of the line drawn through the upper and lower points of contact between curved inner wall 60 of ring 50 and the surface of sphere 12 is such that when the lines formed thereby are extended upwardly and through insert 8 and spherical cup 6, such lines converge. Thus, as shown at lines a, b, FIG. 4 formed by the upward projection of the slope of insert wall 44, ring wall 56 and the upward projection of a line drawn through the upper and lower extremities of the line of contact between inner wall 60 of ring 50 and the surface of sphere 12, with ring 50 and sphere 12 in place, as shown in FIG. 4, sphere 12 tends to force or urge ring 12 downward along wall 44 of insert 8, wedging ring 50 between wall 44 and sphere 12 and locking sphere 12 in the domed cavity of insert 8 when disassembly is attempted. The greater the force applied by sphere 12 to split ring 50, such as the force applied which could otherwise dislocate sphere 12, the greater the wedging force applied to ring 50 by sphere 12 and the greater the resistance to the displacement or dislocation of sphere 8 from insert 8 and cup 6.

The femoral hip prosthesis device of the instant invention is assembled by first inserting plastic insert 8 into spherical cup 6 and then snapping ring 26 on cup 6 into recess 34 in insert 8. Insert 8 is then locked in cup 6 with spherical dome 30 of insert 8 in contact with inner spherical dome 22 of cup 6. Sloping wall 38 of insert 8 slopes downwardly and inwardly below the end wall of metal, spherical cup 6, preventing contact of such cup end wall with bone and body tissue, as will be later described.

With insert 8 in cup 6 and locked therein by the interengagement of cup ring 26 with insert recess 34, split ring 50 is inserted through the open end of plastic insert 8 and the end of sphere 12 is inserted into the open end of insert 8. As the dome of sphere 12 enters the cavity in insert 8 and contacts wall 69 of ring 50, ring 50 is raised, wall 54 of ring 50 engages inwardly extending wall 42 of insert 8 and ring 50 expands, allowing sphere 12 to enter the cavity of insert 8 and permitting the spherical surface of sphere 12 to be brought into contact with spherical dome 40 in insert 8. With the dome of sphere 12 in contact with spherical dome 40 of insert 8, the memory of the split ring causes split ring 50 to contract and slide downwardly along sloping wall 44 and locking sphere 12 in insert 8. As has already been noted, the wedging of ring 50 between insert wall 44 and sphere 12 locks sphere 12 in the domed cavity of insert 8 and prevents sphere 12 from being displaced or dislocated from insert 8 and cup 6.

In surgical implant of the device, cup 6 and insert 8 might be assembled and positioned in the acetabulum or hip socket 4. Sphere 12, neck 14 and stem 16 might then be fixed to the thigh bone by implanting stem 16 in thigh bone 18. Next, split ring 50 and sphere 12 might be assembled in the cup 6 already assembled in insert 8 in hip socket 4. The prosthetic device of the invention might also be fully assembled, stem 16 inserted and attached to thigh bone 18 and the outer spherical surface 20 of cup 6 might then be inserted into the acetabulum or hip socket 4.

Once assembled, spherical cup 6, plastic insert 8 and sphere 12, with neck 14 and stem 16, function as a unit. That is, sphere 12 cannot be removed or displaced from insert 8 and insert 8, with sphere 12 in place, cannot be separated or dislocated from cup 6. Thus, any unusual force which might be applied to the prosthetic device of the instant invention, once the device is surgically implanted which would cause displacement or dislocation, will result in the dislocation of the prosthetic hip joint of

the invention as a unit much in the same manner as would occur at the joint in a natural hip. In other words, the device of the instant invention will remain as a unit and will be displaced as a unit from the acetabulum or hip socket 4 at cup 6. The hip prosthesis of the instant invention, should it become displaced or dislocated, can be restored to its proper position by manipulating the leg or thigh bone in the same manner as in the relocation of a dislocated natural hip. The sloping wall 38 of the plastic insert, extending over and covering the end of the spherical cup 6, guides the prosthetic device back into place and prevents damage to body and bone tissue when the prosthetic device of the instant invention is being manipulated, in conventional manner, to relocate a displaced hip joint.

Once the device of the instant invention has been assembled and surgically implanted, disassembly of the device should not be necessary. However, should it become necessary or desirable to disassemble the unit, a screw driver or surgical instrument can be inserted through slot 45 at the end of sloping wall 44 of insert 8 and split ring 50 can be forced upwardly and expanded outwardly around sphere 12. A plurality of such slots spaced around split ring 50 may be provided to better guide and expand the split ring during such expansion. With split ring 50 elevated in insert 8, as shown in FIG. 3, sphere 12 can be withdrawn, through split ring 50, from insert 8.

The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed.

What is claimed:

1. An implantable prosthetic joint for use in replacement of the ball end of a biological joint, said prosthetic joint having a metal spherical head for insertion into and seating in the natural socket of the joint, a bearing insert in said spherical head, said bearing insert having an outer spherical dome for engagement with the inner surface of said metal spherical head, an inner spherical dome and an outwardly extending recess at the entrance end of said inner spherical dome extending circumferentially around said entrance end and having an outwardly extending end wall and an outer wall extending downwardly from said end wall and sloping downwardly and inwardly toward said entrance, a ball shaped member seated in said inner spherical dome of said bearing insert and a ring intermediate said bearing insert and said ball shaped member, said ring having an end wall and an outer wall sloping downwardly and inwardly and in contact with said outer wall of said insert recess and an arcuate wall in contact with said ball shaped member, the length of said outer sloping wall of said ring being substantially shorter than the outer sloping wall of said recess in said bearing insert and permitting said ring to slide upwardly and expand in said recess in said bearing insert until said ball passes through said ring as said ball shaped member is inserted through the entrance end into said insert and to permit said ring to slide downwardly in said recess away from said recess end wall and wedge between said outer sloping wall of said recess and said ball shaped member when force is applied to said ball shaped member to withdraw said ball shaped member from said insert to lock said ball shaped member in said bearing insert and to permit said ring to be pushed by an unlocking tool upwardly in said recess in said bearing insert toward said outwardly extending end wall of said recess to permit said ring to be expanded outwardly sufficiently for said ball shaped member to be withdrawn through said ring and from said insert.

2. An implantable prosthetic joint, as recited in claim 1, in which said ring is a split ring.

3. An implantable prosthetic joint, as recited in claim 2, in which said outer sloping wall of said recess at the entrance end of said inner spherical dome has a recess for receiving an instrument for sliding said ring upwardly in said recess to release said ball shaped member from contact with said inner spherical dome of said bearing insert.

4. An implantable prosthetic joint, as recited in claim 3, in which the inner surface of said metal spherical head has a downwardly extending skirt and an inwardly extending ring extending circumferentially around said skirt and said bearing insert has an inwardly extending recess for engagement with said inwardly extending ring for locking said bearing insert in said spherical head when said outer spherical dome of said bearing insert is in engagement with the inner surface of said metal spherical head.

5. An implantable prosthetic joint, as recited in claim 4 in which the lines formed by projecting the slope of the outer walls of said insert and said ring and the slope of a line drawn through the end points of the contact of said arcuate wall of said ring with said ball shaped member and extending upwardly through said bearing insert and said metal spherical head merge toward each other.

6. An implantable prosthetic joint as recited in claim 5 in which said bearing insert is of inert, low friction, plastic material.

7. An implantable prosthetic joint, as recited in claim 6 in which said plastic is selected from the group consisting of high molecular weight polyethylene and high molecular weight polypropylene.

8. An implantable prosthetic joint, as recited in claim 1, in which said ball shaped member includes a neck and a stem for mounting said ball shaped member on the biological member on whose end the ball is being replaced.

9. An implantable prosthetic joint, as recited in claim 8, in which said bearing insert has an outwardly extending portion at its entrance end, said outwardly extending portion extending outwardly along the end of said metal spherical head and forming a guard therefor.

10. An implantable prosthetic joint for use in replacement of the ball end of a biological joint, said prosthetic joint having a spherical head for insertion into and seating in the natural socket of the prosthetic joint, a bearing insert in said spherical head having an inner spherical dome and an outwardly extending recess at the entrance end of said inner spherical dome extending circumferentially around said entrance end and having an outwardly extending end wall and an outer wall extending downwardly from said end wall and sloping downwardly and inwardly toward said entrance, a ball shaped member seated in said inner spherical dome of said bearing insert and a ring intermediate said bearing and said ball shaped member, said ring having an end wall and an outer wall sloping downwardly and inwardly and in contact with said outer wall of said insert recess and an arcuate wall in contact with said ball shaped member, the length of said outer sloping wall of said ring being substantially shorter than the outer slop-

ing wall of said recess in said bearing insert and permitting said ring to slide upwardly and expand in said recess in said bearing insert until said ball passes through said ring as said ball shaped member is inserted through the entrance end into said insert and to permit said ring to slide downwardly in said recess away from said recess end wall and wedge betweenn said outer sloping wall of said recess and said ball shaped member when force is applied to said ball shaped member to withdraw said ball shaped member from said insert to lock said ball shaped member in said bearing insert and to permit said ring to be pushed by an unlocking tool upwardly in said recess in said bearing insert toward said outwardly extending end wall of said recess to permit said ring to be expanded outwardly sufficiently for said ball shaped member to be withdrawn through said ring and from said insert.

11. An implantable prosthetic joint, as recited in claim 10, in which said ring is a split ring.

12. An implantable prosthetic joint, as recited in claim 11, in which said outer sloping wall of said recess at the entrance end of said inner spherical dome has at least one recess for receiving an instrument for sliding said ring upwardly in said recess to release said ball shaped member from contact with said inner spherical dome f said bearing insert.

13. An implantable prosthetic joint, as recited in claim 12 in which the lines formed by projecting the slope of the outer walls of said insert and said ring and the slope of a line drawn through the end points of contact between the arcuate wall of said ring with said ball shaped member upwardly through said spherical head converge toward each other.

14. An implantable prosthetic joint, as recited in claim 10, in which said ball shaped member includes a neck and a stem for mounting said ball shaped member on the biological member on whose end the ball is being replaced.

15. An implantable prosthetic joint, as recited in claim 14, in which said insert has an outwardly extending portion at its entrance end, said outwardly extending portion extending outwardly along the end of said spherical head and forming a skid therefor.

* * * * *

US006309391B1

(12) **United States Patent**
Crandall et al.

(10) **Patent No.: US 6,309,391 B1**
(45) **Date of Patent: Oct. 30, 2001**

(54) **MULTIDIRECTIONAL PIVOTING BONE SCREW AND FIXATION SYSTEM**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.**[7] **A61B 17/56**
(52) **U.S. Cl.** **606/61**; 606/73
(58) **Field of Search** 606/61, 72, 73

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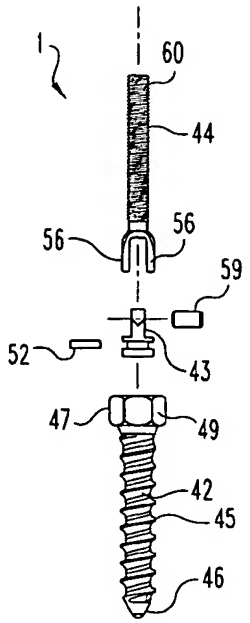
Primary Examiner—Paul J. Hirsch
Assistant Examiner—Melba Bumgarner
(74) *Attorney, Agent, or Firm*—Woodard, Emhardt, Naughton Moriarty & McNett

(57) **ABSTRACT**

A double-jointed bone bolt for use in an apparatus for maintaining vertebra in a desired relationship. The apparatus has a rod that extends substantially along the spine and one or more bone bolts. At least one of the bone bolts is double jointed. The double-jointed bolt has a mounting portion with a hook or coarse threads to engage a vertebra, and the mounting portion is attached to a pivot post in a manner that allows the pivot post to be rotatable about a common axis in respect to the mounting portion. The pivot post of the bone bolt is then pivotally attached to a connector portion of the bone bolt that has machine threads upon which a surgeon may attach a clamp. The clamp has a second bolt and an arm. The second bolt holds the rod and the arm to the clamp. The second bolt has a first channel to attach to the rod, while the arm has a second channel to attach the double-jointed bone bolt.

21 Claims, 11 Drawing Sheets



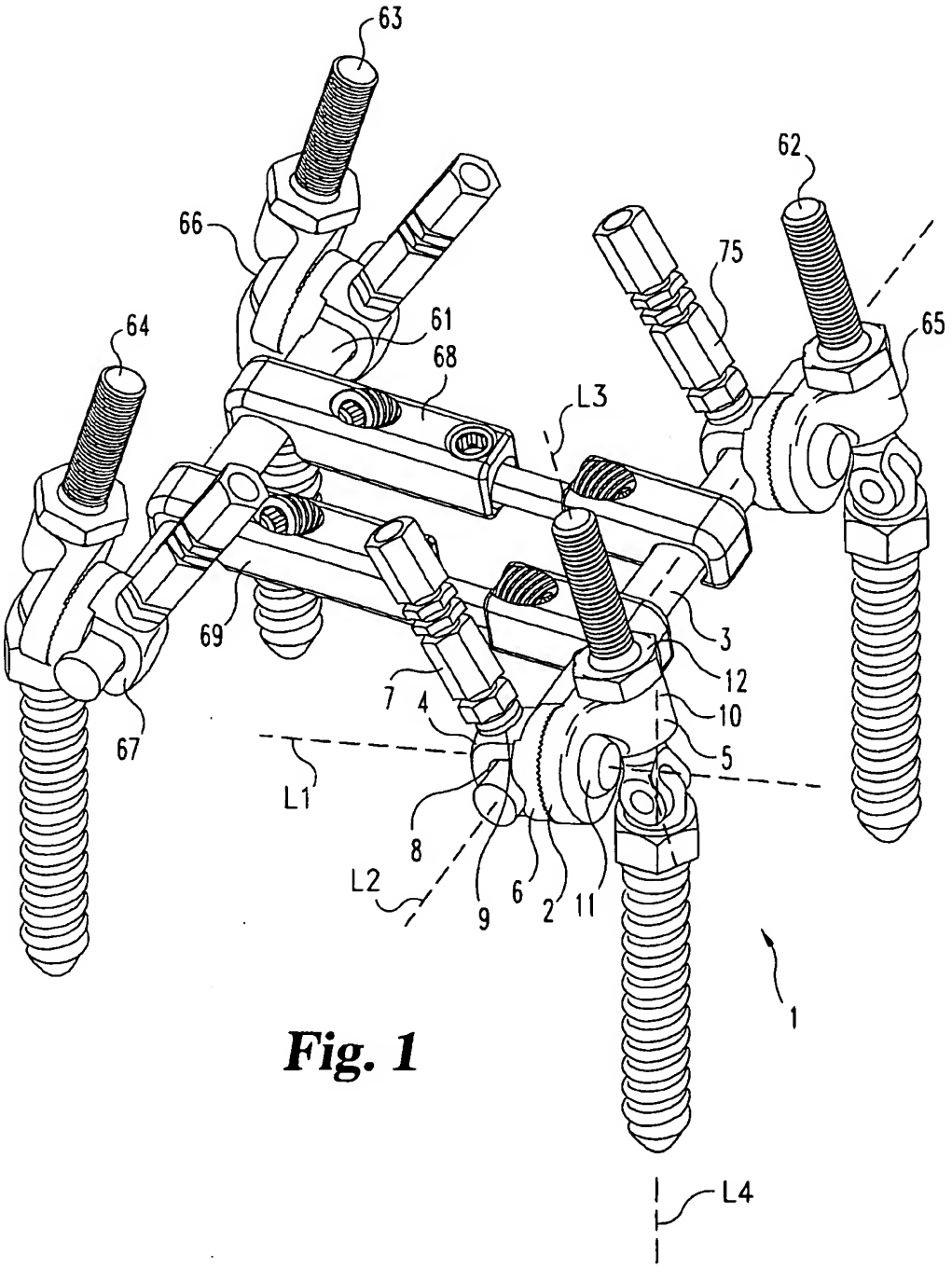


Fig. 1

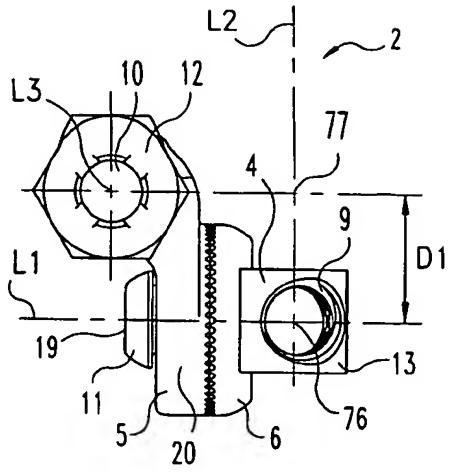


Fig. 2

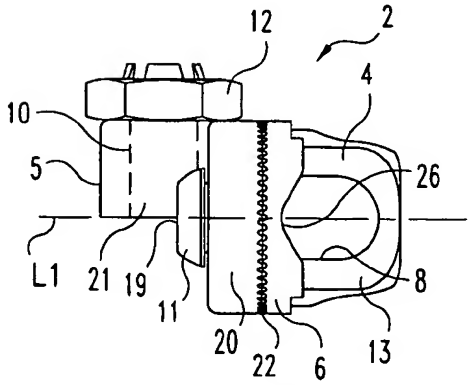


Fig. 3

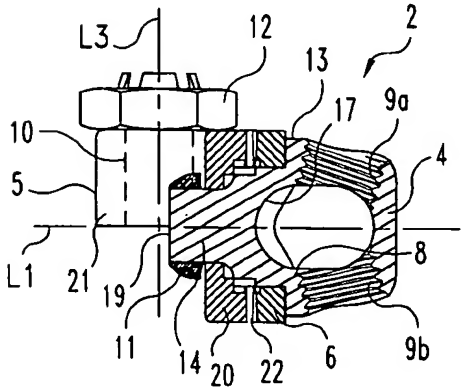


Fig. 4

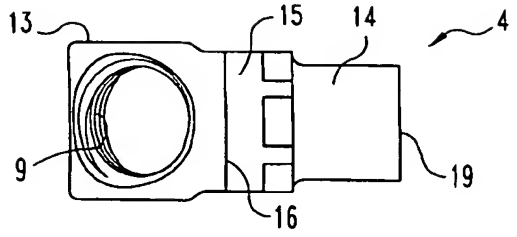


Fig. 5

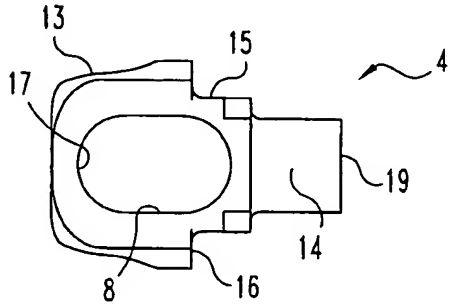


Fig. 6

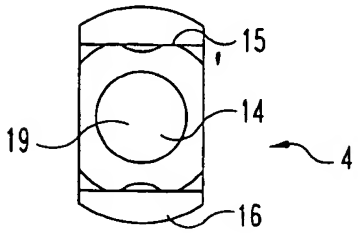


Fig. 7

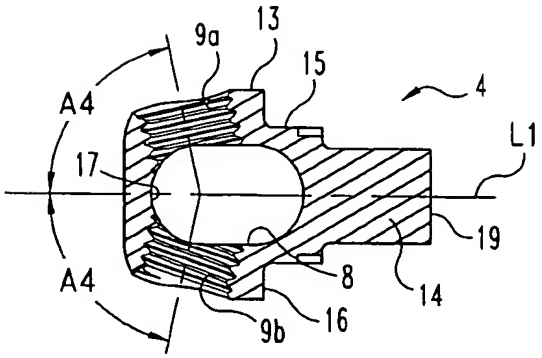


Fig. 8

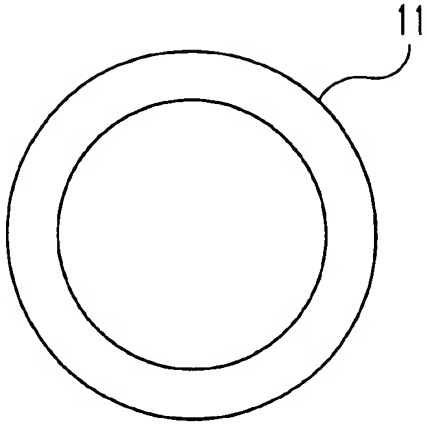


Fig. 9

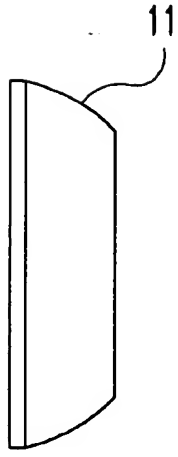


Fig 10

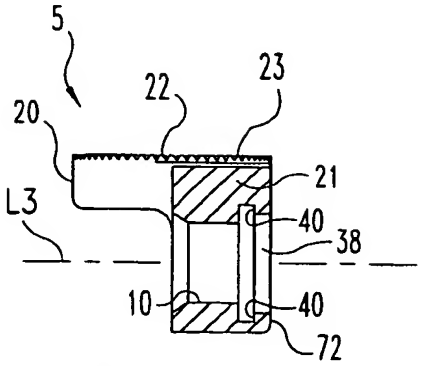


Fig. 11

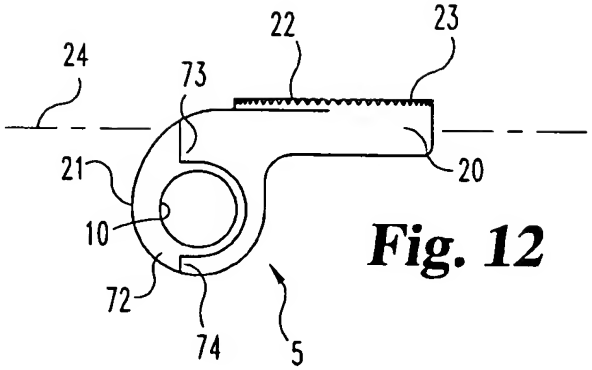


Fig. 12

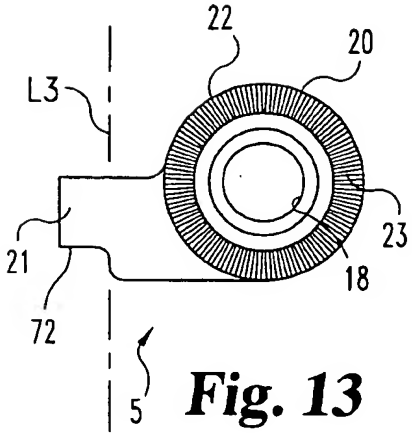


Fig. 13

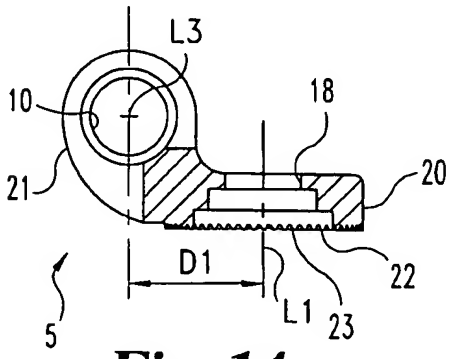


Fig. 14

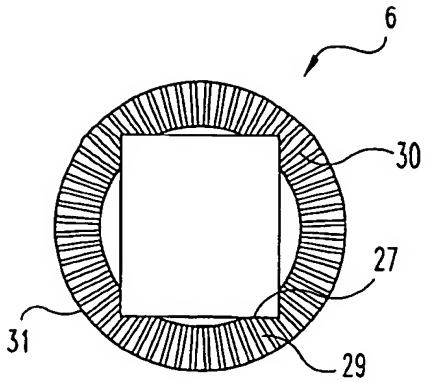


Fig. 15

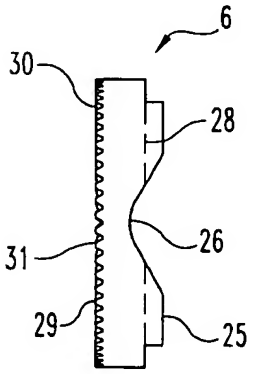


Fig. 16

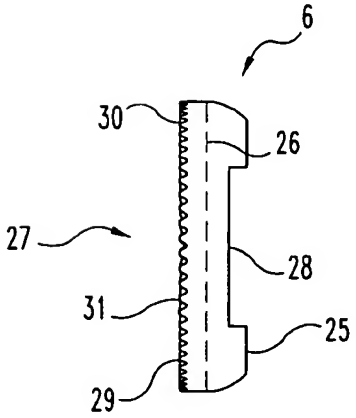


Fig. 17

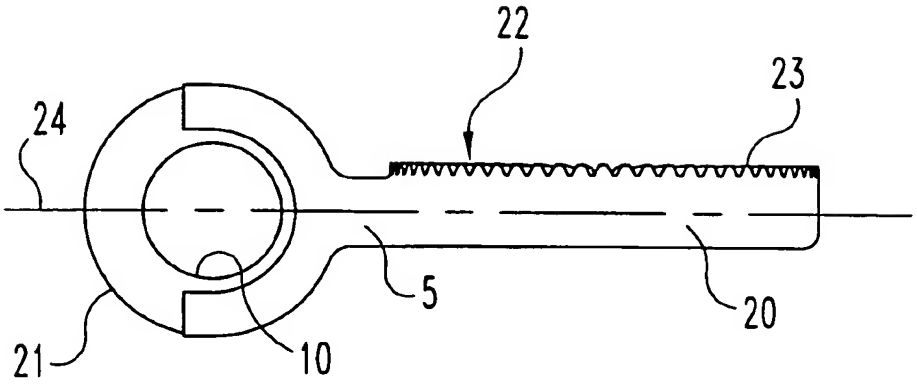


Fig. 18

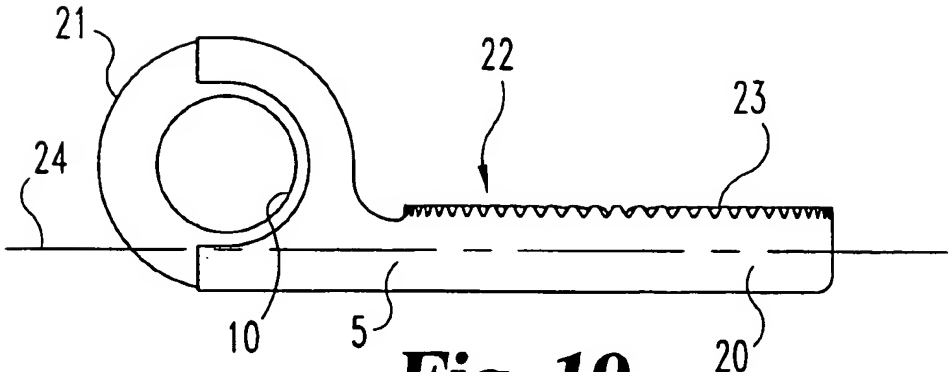


Fig. 19

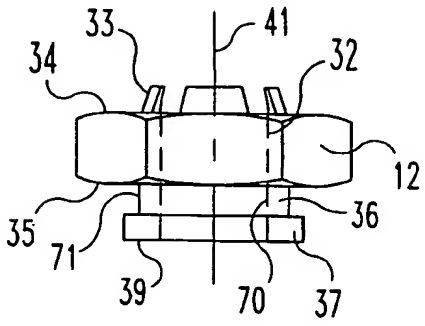


Fig. 20

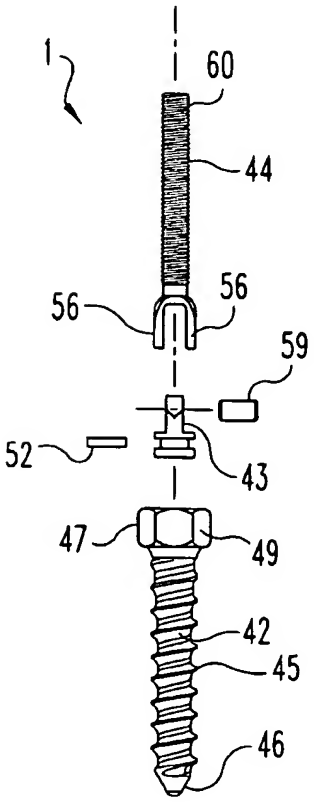


Fig. 21

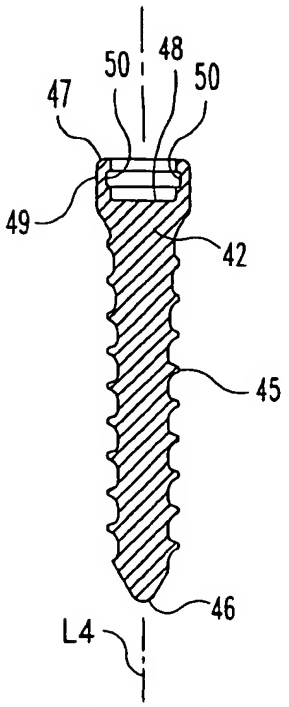


Fig. 22

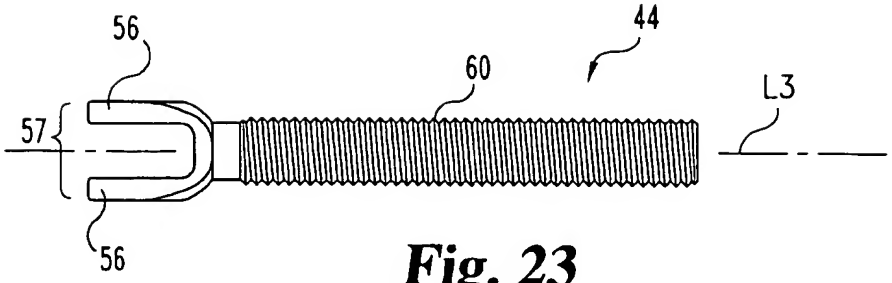


Fig. 23

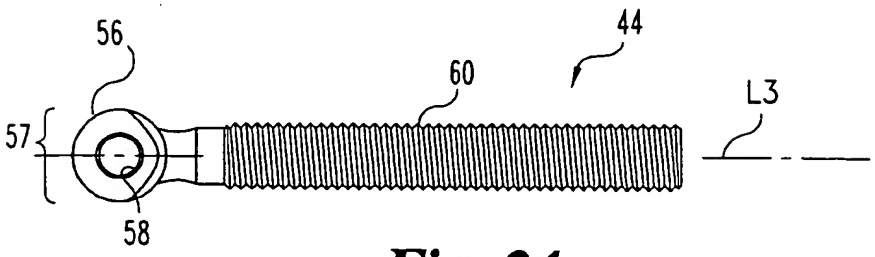


Fig. 24

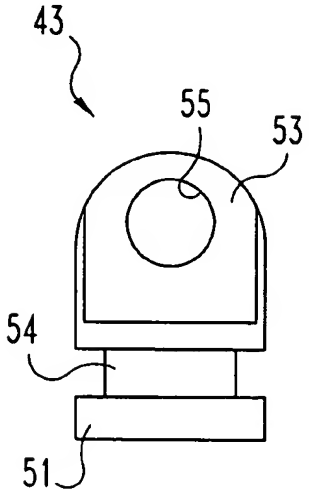


Fig. 25

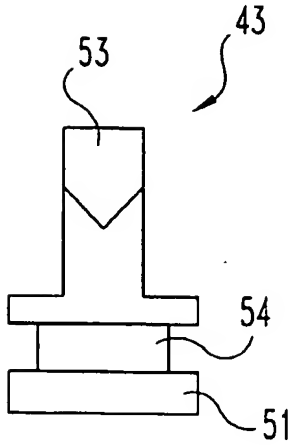


Fig. 26

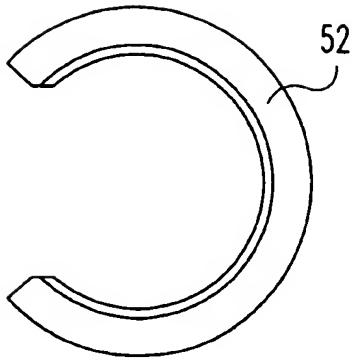


Fig. 27

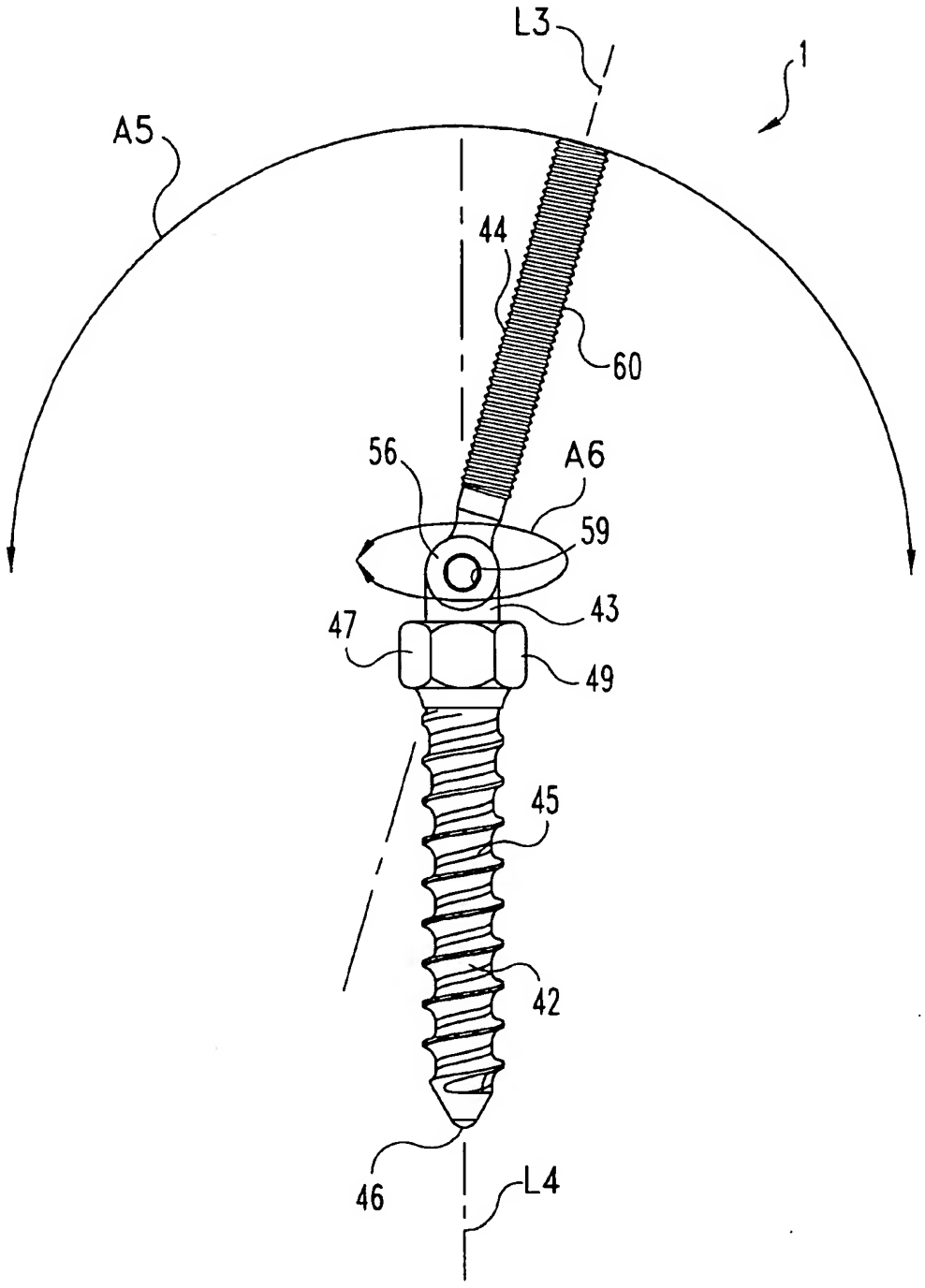


Fig. 28

MULTIDIRECTIONAL PIVOTING BONE SCREW AND FIXATION SYSTEM

This invention relates to orthopedics and spinal surgery, and more particularly relates to a double-hinged bone screw to accommodate the differences in position of adjacent bolts implanted in adjacent vertebrae, which bolts are all mounted to a common spinal rod.

BACKGROUND

Spinal implant systems provide a rod for supporting the spine and properly positioning components of the spine for various treatment purposes. Bolts or screws are typically secured into the vertebrae for connection to a supporting rod. These bolts must frequently be positioned at various angles due to the anatomical structure of the patient, the physiological problem to be treated, and the preference of the physician. It is difficult to provide secure connection between the spinal support rod and these connecting bolts at various angles, and where there are differing distances between the rod and bolts and different heights relative to these components.

SUMMARY OF THE INVENTION

In one aspect, this invention is a bolt for connecting a vertebra to a longitudinal member. The bolt has a mounting portion with a hook or coarse threads to engage a vertebra. The mounting portion is attached to a pivot post in a manner that allows the pivot post to be rotatable about a common axis in respect to the mounting portion of the bolt. The pivot post is then pivotally attached to a connector portion that has machine threads upon which a surgeon may attach other structures.

In another aspect, this invention is an apparatus for maintaining vertebra in a desired relationship. The apparatus has a rod that extends substantially along the spine and one or more bone bolts. At least one of the bone bolt has a mounting portion with a hook or coarse threads to engage a vertebra, and the mounting portion is attached to a pivot post in a manner that allows the pivot post to be rotatable about a common axis in respect to the mounting portion of the bolt. The pivot post of the bone bolt is then pivotally attached to a connector portion of the bone bolt that has machine threads upon which a surgeon attaches a clamp. The clamp, also a part of this embodiment of the invention, has a second bolt and an arm. The second bolt holds the rod and the arm to the clamp. The second bolt has a first channel to hold the rod while the arm has a second channel to hold the bone bolt.

It is an object of this invention to provide a connection assembly that will allow connection between a spinal support rod to a vertebra at a variety of angles relative to the vertical, taken when the patient is lying down.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of the present invention.

FIGS. **2–4** are respectively top, side, and cross-sectional views of a clamp that may be used in one embodiment of the present invention.

FIGS. **5–8** are respectively, top, side, end, and cross-sectional views of a clamp bolt that may be used in one embodiment of the present invention.

FIGS. **9–10** are respectively end and side views of a stop that may be used in one embodiment of the present invention.

FIGS. **11–14** are respectively end cross-sectional, top, side, and side cross-sectional views of an arm that may be used in one embodiment of the present invention.

FIGS. **15–17** are respectively end, side, and top views of a washer that may be used in one embodiment of the present invention.

FIGS. **18, 19** are top views of alternative embodiments for an arm in the practice of the present invention.

FIG. **20** is a side view of a nut that may be used in one embodiment of the present invention.

FIG. **21** is an exploded view of a bone bolt in one embodiment of the present invention.

FIG. **22** is a cross-sectional view of a mounting portion of a bone bolt according to one embodiment of the present invention.

FIGS. **23** and **24** are respectively side and top views of a connecting portion of a bone bolt according to one embodiment of the present invention.

FIGS. **25** and **26** are respectively front and side view of a pivot post in a bone bolt according to one embodiment of the present invention.

FIG. **27** is a top view of a snap ring for a bone bolt according to one embodiment of the present invention.

FIG. **28** is a side view of a bone bolt according to one embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Specific language is used in the following description to publicly disclose the invention and to convey its principles to others. No limits on the breadth of the patent rights based simply on using specific language are intended. Also included are any alterations and modifications to the description that should normally occur to one of average skill in this technology.

A bone bolt **1** according to one embodiment of the invention is shown as part of a larger spinal implant system in FIG. **1**. Bone bolt **1** is shown attached to a clamp **2** with the longitudinal axis L1, and clamp **2** is shown attached to a spinal implant rod **3** with a longitudinal axis L2. Clamp **2** includes a clamp bolt **4**, an arm **5**, a rod interface washer **6**, a set screw **7**, and a nut **12**. Clamp bolt **4** has an aperture **8** for receiving rod **3**, and while the aperture is shown closed around rod **3**, it will nevertheless be understood that an open-sided aperture may also be used to permit top-loading of rod **3** into clamp **2**. Set screw **7** is inserted through a threaded opening **9** and into aperture **8** in clamp bolt **4** so as to allow set screw **7** to push against rod **3**. Arm **5** has a bore **10** for receiving bone bolt **1**. Arm **5** is simultaneously tightened to clamp **2** when set screw **7** is tightened against rod **3**. As set screw **7** pushes against rod **3**, rod **3** pushes against rod interface washer **6**, which pinches arm **5** between rod interface washer **6** and stop **11**. In this manner, set screw **7** acts as a compression member to tighten clamp **2** and achieve substantial fixation of arm **5** to rod **3**.

Details of clamp bolt **4** are shown in FIGS. **2–8**. Clamp bolt **4** can be subdivided into bolt head portion **13**, bolt shaft portion **14**, washer seat portion **15** and washer stop portion **16**. Threaded openings **9***a* & **9***b*, and aperture **8** reside in bolt head portion **13**. Threaded openings **9***a* & **9***b* open into aperture **8** at an oblique angle A4 with respect to longitudinal axis L1 to allow set screw **7** (FIG. **1**) to force spinal rod **3** toward the distal end **17** of aperture **8**. Clamp bolt **4** is substantially symmetrical about longitudinal axis L1 such that threaded openings **9***a* and **9***b* are substantially mirror

images. Bolt shaft portion 14 is generally cylindrical in shape and is sized to accept the eye 18 (FIGS. 13 & 14) of arm 5. Arm 5 is then held on shaft portion 14 by attaching stop 11 (shown in isolation in FIGS. 9 & 10) to the end 19 of shaft portion 14, either by welding or some other suitable means. As an alternative, shaft portion 14 may include threads and stop 11 may be correspondingly threaded onto shaft portion 14 to hold arm 5 in position. In this alternative design, stop 11 may be the compressive member utilized to tighten clamp 2 onto rod 3 instead a set screw threaded into bolt head portion 13.

Clamp bolt 4 also preferably includes washer seat portion 15 and washer stop portion 16. A washer seat portion 15 that is substantially rectangular in cross-section is currently preferred, but washer seat portion 15 can be of any suitable shape that may interlock with a complementary shape in rod interface washer 6 (FIGS. 1, 15, 16 & 17) to prevent rod interface washer 6 from rotating in relation to clamp bolt 4. As shown, a washer stop 16 is generally provided in clamp bolt 2 by placing a raised edge in bolt head portion 13. Washer stop 16 prevents rod interface washer 6 from being inadvertently removed from clamp 2.

Details of arm 5 are shown in FIGS. 11–14. Arm 5 includes a flange portion 20, and a collar portion 21. Flange portion 20 has an eye 18, and as previously presented, clamp bolt 4 attaches to arm 5 by placing the shaft portion 14 of clamp bolt 4 through eye 18 and then attaching stop 11 on end 19 of shaft portion 14. The medial face 22 of flange portion 20 also includes a connection surface 23. Connection surface 23 preferably includes structure for facilitating the engagement of arm 5 against rotational movement relative to rod interface washer 6. This engagement structure is preferably a plurality of variable angle ridges that radiate from the rotational center of eye 18. In other words, the structure is a set of interlocking teeth that can generally be characterized as male protrusions and complementary female cavities that upon interlock, prevent rod interface washer 6 from rotating in respect to arm 5.

Referring to FIGS. 12, 18 and 19; collar portion 21 of arm 5 has a bore 10. Bore 10 may assume various orientations in relation to the centerline 24 of arm 5. FIG. 12 depicts bore 10 offset from centerline 24 toward the stop (not shown) of clamp bolt 4. Optionally, bore 10 can be offset from centerline 24 toward the clamp aperture 8 (not shown) of clamp bolt 4, as shown in FIG. 19, or bore 10 can be placed in the same plane as centerline 24, as shown in FIG. 18. It being understood that the alternative arm designs may permit even a smaller total width of clamp 2 by bringing bone bolt 1 closer to the rod 3.

Referring to FIG. 20, there is shown nut 12, which is preferably used to threadably engage bone bolt 1 (not shown) to arm 5, and prevent bone bolt 1 from moving longitudinally along longitudinal axis L3 with respect to arm 5. Nut 12 has as set of internal threads 32 to mate with the machine threads 60 on bone bolt 1 and a set of locking tabs 33 on the proximal face 34 of nut 12 to firmly hold nut 12 upon bone bolt 1 once nut 12 is threaded into place. The distal face 35 of nut 12 also includes an annular collar 36. Annular collar 36 is integrally connected to nut 12, and has a channel 70 that opens into internal threads 32. The end 39 of collar 36 terminates in an annular rim 37 that laterally projects beyond the diameter of annular collar 36, and forms an annular groove 71 between annular rim 37 and distal face 35 of nut 12.

Referring back to FIGS. 11–14, arm 5 is preferably adapted to rotatably secure nut 12 by annular rim 37 and annular collar 36. The proximal face 72 of collar portion 21 of arm 5 includes a semicircular cavity 38 around the entrance of bore 10 that is sized to accept annular collar 36 and annular rim 37. By fitting collar 36 and rim 37 into cavity 38, annular rim 37 rides against semi-circular lip 40, on the roof of cavity 38; opening 70 and internal threads 32 of nut 12 are axially aligned with bore 10 of arm 5; and nut 12 is rotatably secured to arm 5. In other words, nut 12 is free to rotate about axis 41 or axis L3, but nut 12 is substantially fixed against movement along longitudinal axis L3 (FIGS. 11 & 13) relative to arm 5 because annular rim 37 rides against semi-circular lip 40 in one direction and proximal face 72 in the other. In one preferred embodiment, nut 12 is temporarily held in semicircular cavity 38 by slightly bending corners 73 & 74 of lip 40 against annular rim 37. Bending these corners will temporarily hold nut 12 in arm 5 until the surgeon threads nut 12 onto bone bolt 1, and will not significantly hinder the surgeon's rotation of nut 12 around bone bolt 1.

Details of rod interface washer 6 are shown in FIGS. 15, 16 & 17. Rod interface washer 6 can be any of several suitable shapes, including the circle that is depicted. The medial face 25 of the rod interface washer 6 has an engagement surface, which preferably includes an engagement groove 26 that accepts a cylindrical spinal implant rod (such as rod 3 in FIG. 1). Engagement groove 26 preferably runs across the entire face of medial face 25. Rod interface washer 6 also has a central opening 27 that corresponds to the cross-sectional shape of previously presented washer seat portion 15 in clamp bolt 4. In the currently preferred embodiment, both washer seat portion 15 and opening 27 are substantially square. Although, this shape could vary from many possible shapes that would similarly prevent rod interface washer 6 from rotating in respect to clamp bolt 4. To assist in this regard, it is also preferable that rod interface washer have a guide groove 28 to accept bolt head portion 13 of clamp bolt 4 to further lock clamp bolt 4 and rod interface washer 6 together. It should be noted that guide groove 28 and engagement groove 26 are preferably placed in such a manner that orients aperture 8 substantially parallel to groove 26. This placement helps insure that spinal rod 3 will be held in the connector assembly in a direction that is substantially perpendicular to clamp bolt 4, and in turn, also substantially perpendicular to set screw 7.

Rod interface washer 4 also includes connection surface 29 on the lateral face 30 of rod interface washer 6. Connection surface 29 preferably includes structure for facilitating the engagement of rod interface washer 6 against rotational movement relative to arm 5. This engagement structure is preferably a plurality of variable angle ridges 31 that radiate from the rotational center of rod engagement washer 6, similar to those previously described on the medial face 22 on flange 20 of arm 5. Variable angle ridges 31 are sized to mate with the similar variable angle ridges 23 on arm 5. Referring to FIGS. 13 and 15, both sets of ridges consist of alternating male protrusions and female cavities. Hence, once placed together, these interlocking ridges prevent rod engagement washer 6 from rotating in respect to arm 5. And although radiating ridges are shown to facilitate the fixation of these two parts, it is also contemplated that other structures could serve this function. For example, it is also contemplated that one could use any number of interlocking male and female structures such as rounded bumps or knurling and mating cavities. The locking engagement of connection surface 23 with connection surface 29 may occur at any of a plurality of angles. More specifically, the angle between longitudinal axis L3 of bone bolt 1 and the longi-

tudinal axis L2 of rod 3 may be adjusted to meet the requirements of the patient's anatomy.

Details of bone bolt 1 can be seen in FIGS. 21–28. Bone bolt 1 includes a mounting portion 42, a pivot post 43, and a connector portion 44. The distal end of mounting portion 21 has a set of coarse threads 45. Coarse threads 45 have a thread convolution for engaging cancellous bone and terminate in a tapered tip 46. Tapered tip 46 helps align bone bolt 1 into a predrilled opening in a vertebra and also helps coarse threads 45 to gradually engage and advance into the vertebra upon rotation of mounting portion 21. In this regard, although coarse threads are shown as a means for engaging a vertebra, it is also contemplated that a hook, mounted on the end of mounting portion 42, could also be used as an alternative means to engage a vertebra. The proximal end 47 of mounting portion 42 terminates in hex-headed drive portion 49. The inside of hex-headed drive portion 49 includes an annular receptacle 48, and the inner wall of receptacle 48 has an annular groove 50. (FIG. 22) Annular receptacle 48 is sized to accept hub 51 of pivot post 43 (FIGS. 25 & 26), and annular groove 50 is sized to accept snap ring 52. (FIG. 27)

Pivot post 43 is shown in isolation in FIGS. 25 & 26. Pivot post 43 has a hub 51 and an ear 53 with a channel 55. Hub 51 preferably has a circular cross-section and is circumscribed by an annular groove 54. Hub 51 is sized to freely rotate about longitudinal axis L4 inside receptacle 48 of the mounting portion 42 of bone bolt 1. During assembly in one preferred embodiment, snap ring 52 (FIG. 27) is placed partly inside annular groove 54 before hub 51 is inserted into receptacle 48. Then, upon insertion into receptacle 48, snap ring 52 partially expands into annular groove 50, and thereby rotatably connects pivot post 53 to the proximal end 47 of mounting portion 42.

A top and side view of the connector portion 44 of bone bolt 1 is shown in FIGS. 23 & 24. Most of the longitudinal length of connector portion 44 is circumscribed with machine threads 60. The lower end 57 of connector portion 44 terminates with a pair of ears 56 that are diametrically opposite of each other at the radial perimeter of end 57. Each of the ears 56 includes an aperture or channel 58 for insertion of pin 59 (FIG. 21). During assembly, pin 59 is inserted through aperture 58 in one ear, then through channel 55 in pivot post 43, and then through aperture 58 in the other ear. Thusly joined to mounting portion 42 and pivot post 43, the connector portion 44 of bolt 1 may be pivoted around pin 59 as depicted by arc A5, and may also be rotated around longitudinal axis L4 of the mounting portion 42, as depicted by arc A6. (FIG. 28)

Referring back to FIG. 1, a typical construct in the use of this invention typically has two or more largely identical rods, 1 and 61, and at least two or more bone bolts 1, 62–64 attached to each rod by clamps 2, 65–67. And optionally, the rods may be joined by one or more cross-linking members 68 & 69. An example of a suitable cross-linking member is described in U.S. Pat. No. 5,947,966 to Drewry et al, the disclosure of which is specifically incorporated into this specification by reference. And although each of the clamps and bone bolts shown in this figure are identical, it is further contemplated that other clamps and bone bolts could be incorporated in a common construct in the use of this invention. For example, one could also use the clamps and bone bolts described in U.S. Pat. Nos. 5,643,263 and 5,885,285 to Simonson, the disclosures of which are specifically incorporated into this specification by reference with one or more of the bone bolts described herein.

Clamp 2 is depicted in FIGS. 2–4, less set screw 7, which has been removed for clarity along with rod 3 and bone bolt 1. The clamp is used by placing spinal rod 3 through aperture 8. The connector portion 44 of bone bolt 1 is then threaded through bore 10 and nut 12 of clamp 2 as the surgeon desires. Arm 5 and the variable angle ridges 31 on the rod interface washer 6 are then interlocked with the variable angle ridges 23 on arm 5, and the assembly is tightened by threading set screw 7 into either of the threaded openings 9, (or by optionally turning stop 11 around connector portion 44 as described in an alternative embodiment). Upon entering aperture 8, set screw 7 contacts the spinal rod and forces the spinal rod toward interface washer 6. The spinal rod then contacts rod interface washer 6, and engages groove 26. As one continues turning set screw 7, rod interface washer 6 presses flange portion 20 of arm 5 against stop 11. The variable angle surfaces, item 23 on arm 5 and item 31 on rod interface washer 6, firmly engage each other and prevent rod interface washer 6 from rotating in relation to arm 5, which further locks arm 5 in relation to clamp bolt 4 because rod interface washer 6 cannot rotate in relation to clamp bolt 4. Adjustments can be made by loosening set screw 5 then re-tightening the set screw when the preferred position has been located. The surgeon can adjust the longitudinal position of bone bolt 1 by rotating nut 12 as the surgeon desires. The set screws 7 shown in FIG. 1 are of a type that shear at 75 when the appropriate amount of torque has been placed on set screw 7. Such set screws are now well-known in this art.

Referring to FIGS. 1 & 2, one may note some additional features of this invention by noting the locations of various longitudinal axes. L1 is the longitudinal axis of a portion of clamp 2. L2 is the longitudinal axis of rod 3, and L3 is the longitudinal axis of both connecter portion 44 of bolt 1 and bore 10 in arm 5. In this regard, one may not that L3 is offset from L1 a distance D1. In other words, clamp 2 will contact rod 3 at 76, and L3 or bore 10 spaced from 76 a distance D1 along rod 3. In many circumstances involving patient anatomy, distance D1 may help the surgeon place clamp 2 and/or bone bolt 1 in a manner that avoids interfering with the patient's anatomy, such as the facet joints of the spine.

While the invention has been illustrated and described in detail, this is to be considered as illustrated and not restrictive of the patent rights. The reader should understand that only the preferred embodiments have been presented and all changes and modifications that come with the sprit of the invention are included if the following claims or the legal equivalent of these claims describes them.

We claim:

1. A bolt for connecting a vertebra to a longitudinal member, comprising:

a mounting portion, said mounting portion having means for engaging a vertebra;

a pivot post, said mounting portion and said pivot post being, to one another so as to be rotatable about a connection axis;

a connector portion pivotally attached to said connector post, said pivot portion having machine threads.

2. The bolt of claim 1, including means for attaching a wrench to said mounting portion.

3. The bolt of claim 1, where said mounting portion has a proximal end and said pivot post has a distal end, and the proximal end of said mounting portion and the distal end of said post have mutually engageable male and female contacts, and wherein said contacts are adapted to allow said pivot post to rotate in respect to said mounting portion.

4. The bolt of claim 1, including a snap ring operably connecting said mounting portion and said post.

5. The bolt of claim 1, wherein said mounting portion has a length and said means for engaging are coarse threads disposed over at least a portion of the length of said mounting portion.

6. An assembly for maintaining vertebra in a desired relationship, comprising:

a rod having a first longitudinal axis extending substantially along the spine;

a bone bolt, said bone bolt including a mounting portion, a pivot post and connector portion, said mounting portion having means for engaging a vertebra; said mounting portion and said pivot post being engaged to one another so as to be rotatable about a connection axis; said connector portion pivotally attached to said pivot post, and said connector portion having machine threads and a second longitudinal axis; and

a clamp, said clamp including a second bolt and an arm, said second bolt having a first channel for receiving a portion of the rod and a portion with a third longitudinal axis, said arm joined to said second bolt, said arm having a second channel for receiving the machine threads of said bone bolt.

7. The assembly of claim 6, wherein said second bolt engages said rod at a first longitudinal position and said bone bolt is spaced from said first longitudinal position along the first longitudinal axis.

8. The assembly of claim 6, wherein the second channel in said arm is offset from said third longitudinal axis along the first longitudinal axis.

9. The assembly of claim 6, including a nut rotatably threaded over the machine threads of said bone bolt and rotatably connected to the arm of said clamp.

10. The assembly of claim 6, wherein the second longitudinal axis of said connector portion of said bone bolt is offset from the third longitudinal axis of said portion of said clamp along the first longitudinal axis of said rod.

11. The assembly of claim 6, wherein said arm has a centerline and the second channel of said arm is laterally offset from the centerline toward said rod.

12. The assembly of claim 6, wherein said arm has a centerline and the second channel of said arm is laterally offset from the centerline away from said rod.

13. The assembly of claim 6, wherein said arm has a certerline and the second channel of said arm resides in the same plane as the centerline.

14. The assembly of claim 6, wherein said arm may be fixedly connected in a plurality of positions about said third longitudinal axis.

15. The assembly of claim 6, wherein said clamp includes a rod interface washer positioned over a portion of the second bolt, between the first channel and the arm, said rod interface washer being fixed against rotation relative to said bolt.

16. The assembly of claim 15, wherein said arm and said interface washer have mating male protrusions and female cavities on at least a portion of their surfaces such that, when pressed together, the protrusions and cavities facilitate the engagement of said rod interface washer to said arm, preventing rotation of said arm relative to said rod interface washer.

17. The assembly of claim 6, where said mounting portion has a proximal end and said pivot post has a distal end, and the proximal end of said mounting portion and the distal end of said post have mutually engageable male and female contacts, and wherein said contacts are adapted to allow said pivot post to rotate in respect to said mounting portion.

18. The assembly of claim 17, including a snap ring operably connecting said mounting portion and said post.

19. The assembly of claim 17, wherein said clamp includes a rod interface washer positioned over a portion of the second bolt, between the first channel and the arm, said rod interface washer being fixed against rotation relative to said bolt.

20. The assembly of claim 19, wherein said arm and said interface washer have mating male protrusions and female cavities on at least a portion of their surfaces such that, when pressed together, the protrusions and cavities facilitate the engagement of said rod interface washer to said arm, preventing rotation of said arm relative to said rod interface washer.

21. The assembly of claim 20, wherein said arm may be fixedly connected in a plurality of positions about said third longitudinal axis.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,309,391 B1
DATED : October 30, 2001
INVENTOR(S) : Crandall et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,
Line 54, please remove the comma (,) following the word "being" and insert in lieu thereof -- engaged --.
Line 56, please delete "connector post" and insert in lieu thereof -- pivot post --.
Line 57, please delete "pivot portion" and insert in lieu thereof -- connector portion --.

Signed and Sealed this

Twenty-eighth Day of January, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office